PB89-109490

Guidance for the Reregistration of Pesticide Products Containing Terbufos as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

9 Sep 88

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No. PB89-109490/AS

4. Title and Subtitle
Guidance for the Reregistration of Pesticide Products Containing Terbufos as the Active Ingredient

5. Report Date
September 9, 1988

6.

7. Author(s)
EPA, Office of Pesticide Programs Registration Div.

8. Performing Organization Rept. No.
540/RS-88-121

9. Performing Organization Name and Address
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division TS-767C
401 M Street, S.W.
Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address
Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes
Supercedes PB84-210335

16. Abstract (Limit: 200 words)

This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors
Pesticides, standards, regulations, manfacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement: Publicly Available	19. Security Class (This Report) Unclassified	21. No. of Pages 125
	20. Security Class (This Page) Unclassified	22. Price

(See ANSI-Z39.18) See Instructions on Reverse OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

ATTENTION REPRODUCTION

Broadmeasure pages

Turn pages to read from the right

PB89 109490/AS

Pages:

80, 81, 82, 83, 84 and 47 – 73

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

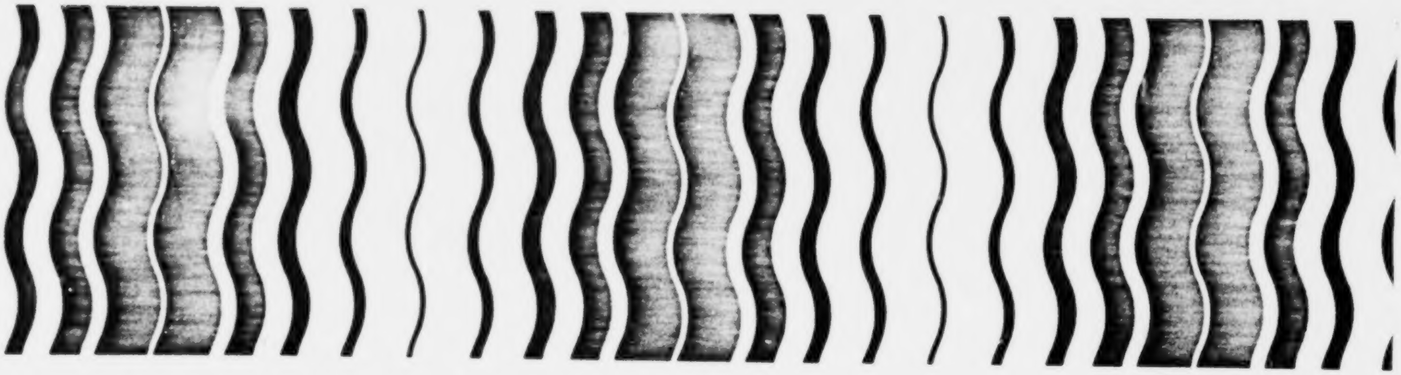
540/RS-88-121

Pesticides

PB89-109490

EPA

Guidance for the Reregistration of Pesticide Products Containing TERBUFOS as the Active Ingredient



REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL INFORMATION SERVICE
SPRINGFIELD, VA. 22161

OMB Control No. 2070-0057
Expires 11/89

REVISED GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

TERBUFOS

AS THE ACTIVE INGREDIENT

CASE NUMBER 0109

CAS Registry Number 13071-79-9

EPA Pesticide Chemical Code (Shaughnessy)
Number 105001

SEPTEMBER 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

i.a

TABLE OF CONTENTS

I. Introduction 1

II. Chemical(s) Covered by this Standard 3
   A. Description of Chemical
   B. Use Profile

III. Agency Assessment 5
   A. Summary
   B. Preliminary Risk Assessment
   C. Environmental Profile
   D. Pesticide Incident Reports
   E. Tolerance Reassessment

IV. Regulatory Position and Rationale. 20
   A. Regulatory Positions
   B. Criteria for Registration
   C. Acceptable Ranges and Limits
   D. Required Labeling

V. Products Subject to this Standard 30

VI. Requirement for Submittal of Generic Data 32
   A. What are generic data?
   B. Who must submit generic data?
   C. What generic data must be submitted?
   D. How to comply with DCI requirements
   E. Registrant Requests Regarding Data Requirements and Agency Responses
   F. Test Protocols and Standards
   G. Procedures for requesting a change in protocol
   H. Procedures for requesting extensions of time
   I. Data Format and Reporting Requirements
   J. Existing stocks provisions upon suspension or cancellation

VII. Requirement for Submittal of Product-Specific Data . . 38

VIII. Requirement for Submittal of Revised Labeling 39

IX. Instructions for Submittal. 39
   A. Manufacturing use products (sole active)
   B. Manufacturing use products (multiple active)
   C. End use products (sole active)
   D. End use products (multiple active)
   E. Intrastate products

APPENDICES

Page

I. DATA APPENDICES 43
Guide to Tables 44
Table A 47
Table B 69

II. LABELING APPENDICES 74
Summary of Label Requirements and Table 75
40 CFR 162.10 Labeling Requirements 85
Physical/Chemical Hazards Labeling Statements . . . 90
Storage Instructions 91
Container Disposal Instructions 92
Pesticide Disposal Instructions 93

III. BIBLIOGRAPHY APPENDICES 94
Guide to Bibliography 95
Bibliography 97

IV. FORMS APPENDICES 111
EPA Form 8580-1 FIFRA §3(c)(2)(B) Summary Sheet 112
EPA Form 8580-6 Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data 113
EPA Form 8580-4 Product Specific Data Report 114
EPA Form 8570-27 Generic Data Exemption Statement . . . 116
EPA Form Certification With Respect to Citation of Data 117

GLOSSARY OF TERMS AND ABBREVATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
ai	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In Notice
EEC	Estimated Environmental Concentration. The estimated pesticide concentration system in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
lb ai/A	Pounds of active ingredient per acre
LEL	Lowest-Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MPI	Maximum Permissible Intake
MRID	Master Record Identification (Number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing-Use Product
NPDES	National Pollution Discharge Elimination System
NOEL	No-Observed-Effect Level
OPP	Office of Pesticide Programs
OES	Office of Endangered Species, U.S. Fish and Wildlife Service

PADI	Provisional Acceptable Daily Intake
ppm	Parts Per Million
RfD	Reference Dose
TMRC	Theoretical Maximal Residue Contribution

I. INTRODUCTION

This document is a revised Registration Standard for the subject chemical. In its original Standard, issued in June 1983, the Agency described the available data supporting the registration of the chemical. The Agency concluded that additional data were necessary to fully evaluate the pesticide. The Agency also set out label language which the Agency concluded at that time were needed to ensure that products containing the pesticide remained in compliance with FIFRA.

The Agency has since received and reviewed the additional data and has revised its scientific and regulatory conclusions in light of those data, other information on the chemical, and expanded data requirements promulgated in 1984, at 40 CFR Part 158, for registration and reregistration of pesticides under FIFRA.

The revised Registration Standard, which supersedes the earlier Standard, is the Agency's updated scientific assessment of the pesticide, and the data needed to support its continued registration. The Agency has also reassessed the tolerances for the pesticide; that reassessment is included in this Registration Standard.

The Agency has also reviewed the current labeling for products containing the pesticide, and has specified label revisions which are necessary to remain in compliance with FIFRA.

The detailed scientific review, which is not contained in this document but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the EPs that contain the ai. The Agency will apply the provisions of this Registration Standard to EPs if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Positions and Rationales. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

---

[1] The scientific reviews and the EPA Compendium of Acceptable Uses may be obtained from the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA. 22161. Phone: (703) 487-4650.

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the DCI provisions of FIFRA section 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA section 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as a product is registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

The following chemical is covered by this Registration Standard:

Common Name: Terbufos
Chemical Name: S-[[(1,1-dimethylethyl)thio]methyl]O,O-diethyl phosphorodithioate
Other Chemical Nomenclature: S-[(tert-butylthio)methyl] O,O-diethyl phosphorodithioate (IUPAC); S-(t-butylthio) methyl O,O-diethylphosphorodithioate (CA, 8th Collective Index); S-tert-butylmercaptomethyl O,O-diethyl dithiophosphate
Trade Names: Contraven; Counter; AC 92,100; CL 92,100; and ST-100
CAS Registry Number: 13071-79-9
EPA Pesticide Chemistry Code (Shaughnessy) Number: 105001
Empirical Formula: $C_9H_{21}O_2PS_3$
Molecular Weight: 288.4
Chemical/Physical Characteristics of a 85% Technical Grade (T) and the Purified Active Ingredient (PAI):
Color: clear, brownish (T)
Physical State: liquid (T)
Odor: mercaptan-like (T)
Specific gravity: 1.105 g/cm^3 at 24 °C
Boiling point: 55 °C at 0.02 mm Hg (T)
Melting point: N/A; technical grade in a liquid at room temperature (T)
Solubility: > 110 g/100 mL in acetone, benzene, chloroform, 1,2-dichloroethene, or ethanol at room temperature (T)
pH: Data gap
Vapor pressure (PAI): 1.15 to 6.06 x 10^{-4} mm Hg at 25 °C,
4.99 to 9.78 x 10^{-4} mm Hg at 35 °C,
9.41 to 16.2 x 10^{-4} mm Hg at 45 °C.
Stability: It is relatively stable in water under neutral or slightly acidic conditions but is subject to hydrolysis under alkaline conditions. It decomposed on prolonged heating at temperatures greater than 120 °C (T).

B. Use Profile

Terbufos, an organophosphate insecticide/nematocide, is principally used as an insecticide for corn rootworms on corn. Other uses include use as a nematocide for lesion, spiral, stunt, sting, stubby-root, and dagger nematodes on corn; and as an insecticide for greenbugs on grain sorghum, sugar beet root maggot on sugar beets, and seedcorn maggots, symphylans, wireworms, maize billbug, southern corn billbug, and reduction of white grubs on corn.

Although terbufos is normally applied as a soil-incorporated treatment using ground equipment, it may be applied as a broadcast treatment on corn using either air or ground equipment. This use is limited to Nebraska, New Mexico, and Iowa.

There are no indoor nor domestic uses registered for the chemical.

There are two Federal registrations for products containing terbufos: one, an MP containing 85.0 percent terbufos, the other, a granular EP containing 15.0 percent ai. There are several Special Local Need Registrations which were issued for 15 percent granular products. There are no intrastate registrations, and no multiple active ingredient formulations registered.

American Cyanamid Company, Agricultural Division, is currently the sole manufacturer of the technical product and formulator of granular EPs in the United States.

C. Regulatory History

Terbufos was first registered for use in the United States in 1974.

In June 1983, the Agency issued the Terbufos Registration Standard setting forth the Agency's regulatory positions based on available data and imposing additional data requirements to support the continued registration of the chemical.

The Terbufos Registration Standard was amended on February 27, 1985 to require restricted use classification labeling for the currently registered 15 percent granular product. This restricted use classification was based on the high acute oral and dermal toxicity to humans.

The registrant has submitted data in response to the Terbufos Registration Standard issued June 1983. These data have been evaluated by the Agency. This revised Registration Standard sets forth the results of the Agency's reassessments of the potential hazards arising from the currently registered uses based on these data.

III. AGENCY FINDINGS

A. Summary

The following is a summary of findings based on the available data. Please refer to the context of EPA's science findings, Sections B through E of this chapter, for further details.

1. Technical terbufos is highly acutely toxic by the oral, dermal, and inhalation routes of exposure, placing it in Toxicity Category I for all three routes.

Because mortality to the test animals would occur prior to the onset of any primary eye or dermal irritation or dermal sensitization, these effects were not evaluated for technical terbufos, and no further data are being required.

The acute delayed neurotoxicity study in chickens was negative for acute neurotoxic effects.

2. Terbufos is a cholinesterase inhibitor, reducing plasma, brain, and red blood cell (RBC) cholinesterase (ChE) activity. Based on the available dog feeding studies, the NOEL for plasma ChE inhibition and brain/RBC ChE, are 0.00125 and 0.060 mg/kg/day, respectively.

3. Results of the available oncogenicity and mutagenicity studies are negative. The Maximum Tolerated Dose (MTD) was reached in the oncogenicity studies.

4. Based on the review of a three-generation rat study using concentrations of 0.25 and 1.0 ppm, the reproductive NOEL for terbufos is considered to be 0.25 ppm. At the 1.0 ppm dose level, there was an increased percentage of litters with offspring deaths as compared with the controls. Because these effects occurred at a dose level which is above the plasma ChE inhibition NOEL established for regulatory purpose, an ample margin of safety exists.

5. Based on the review of a rat teratology study, the NOEL for developmental effects has been tentatively set at 0.1 mg/kg/day. A teratology study in rabbits is needed to fulfill the Guideline requirements. Based on the available rat study, the chemical does not demonstrate a teratogenic potential.

6. Based on results of a rat metabolism study, terbufos was rapidly excreted within 168 hours of administration. Neither the parent compound nor its metabolites accumulated in tissues.

7. The use of terbufos poses a potential risk to loaders and applicators; and to persons reentering treated fields following nonsoil-incorporated broadcast application of the chemical. The major route of exposure is dermal and the Agency is imposing the use of additional protective clothing, a reentry

restriction, and a prohibition against non-soil-incorporated broadcast application on corn prior to any detasseling operations.

8. Laboratory data show that terbufos is highly toxic to avian species and to fish and aquatic invertebrates. Results of level 1 field studies demonstrate the potential for exposure to nontarget organisms and that birds, mammals, reptiles, and fish may be killed by certain applications of terbufos. Level 2, or population studies, are required for the Agency to complete its assessment of the impacts of terbufos to nontarget terrestrial organisms. Aquatic organism field testing and residue monitoring studies are required to complete its assessment of the impacts of terbufos on aquatic organisms.

9. Due to the numerous gaps in residue chemistry data, the Agency is unable to complete a tolerance reassessment of terbufos. The toxicology data requirements to support the tolerances have been met with the exception of a teratology study in rabbits. The reference dose (RfD) for humans is established at 0.000125 mg/kg/ day and the TMRC is estimated to be 0.000052 mg/kg/day which is equivalent to 41.946 percent of the RfD.

10. The Agency is unable to assess the potential for terbufos to contaminate ground water due to the lack of pertinent environmental fate data.

B. Preliminary Health Risk Assessment

The following assessment is based on EPA's review of the available data.

1. Acute Toxicity

Sufficient data are available to classify technical terbufos as Toxicity Category I due to its oral and dermal toxicity with an acute oral toxicity of 1.6 and 1.3 mg/kg for male and female rats, respectively; and an acute dermal toxicity of 0.81 and 0.93 mg/kg for male and female rabbits, respectively. The available repeated (21-day) inhalation study is sufficient to assess the acute inhalation toxicity of terbufos. Based on the mortality observed in the female rats (2/10) and the ChE activity depression observed in both sexes at inhalation exposures which are approximately 2000-fold less than the requirements for Category I ($\leq$ 0.2 mg/L), technical terbufos is classified as Toxicity Category I for acute inhalation toxicity. Technical terbufos was highly toxic to rabbits in primary eye and dermal irritation tests to the extent that all rabbits died within 72 and 24 hours, respectively. A dermal sensitization study is not available and none is required since mortality would occur before sensitization. In an acute delayed neurotoxicity study in hens, there was no evidence of acute delayed neurotoxicity at the 40 mg/kg dosage level tested.

2. Subchronic Toxicity

In a 90-day subchronic oral study, Sprague-Dawley rats were given terbufos in the diet at 0, 0.125 (0.00625 mg/kg), 0.250 (0.0125 mg/kg), 0.50 (0.025 mg/kg) and 1.00 ppm(0.05 mg/kg). The systemic NOEL in this study was determined to be 0.25 ppm based on a significant increase in the liver weight associated with an increase in the incidence of the liver extramedullary hematopoiesis. The NOEL for ChE inhibition was determined to be 0.25 ppm. A subchronic 90-day oral study is not required in the dog because the available chronic dog study in conjunction with the 4-week ChE dog study are sufficient for establishing a ChE NOEL for terbufos.

In a subchronic dermal study, rabbits were exposed for 30 days to dosages of 0.004, 0.02, or 0.10 mg/kg of the technical material. At the lowest effect level of 0.10 mg/kg, edema and erythema were reported. The systemic NOEL was determined to be 0.020 mg/kg. The ChE activity was not determined.

Ninety-day dermal and inhalation studies are not required because repeated dermal or inhalation exposure is not expected to occur from the current registered pesticidal use of terbufos. Since there was no evidence of a neurotoxic effect in the available acute neurotoxicity study, the subchronic neurotoxicity study is not required.

3. Chronic Toxicity and Oncogenicity

In a 2-year feeding/oncogenicity study, female Long Evans strain rats were fed dosages of 0, 0.25 (0.0125 mg/kg), 1.0 (0.05 mg/kg) or 4.0 (0.2 mg/kg) ppm terbufos; male Long Evans strain rats were fed dosages of 0, 0.25, 1.0, 4.0, or 8.0 (0.4 mg/kg) ppm. Both systemic and ChE inhibition effects were observed at the lowest dosage tested (0.25 ppm) and were dose-related. A NOEL could not be determined from this study. There were no oncogenic effects observed in this study.

A 1-year rat study was conducted for purposes of obtaining a NOEL and, though no systemic effects were noted at any dose (the highest dose tested was 1.0 ppm), the NOEL for plasma and brain ChE was 0.5 ppm, which was the mid-dose of the study. The 2-year rat study, when considered in conjunction with the 1-year rat study, satisfies the requirement for a chronic toxicity study in a rodent species.

In an 18-month oncogenicity study, in which groups of 65 male and 65 female Charles River CD-1 mice were fed technical terbufos at dietary levels of 0, 3.0 (0.45 mg/kg), 6.0 (0.90 mg/kg), or 12.0 ppm(1.80 mg/kg), there was no evidence that technical terbufos had an oncogenic effect at any of the dose levels of this study. There was a possible slight increase in mortality as well as a decrease in body weight gain in the high-dose group.

In a 1-year oral study, male and female dogs were administered terbufos in capsule form at dose levels of 0, 15, 60, 90, or 120 ug/kg/day. In this study, consistent, moderate to large depressions in plasma ChE activity occurred in both male and female dogs at all dose levels. Although a NOEL could not be determined for plasma ChE, the systemic NOEL was determined to be 120 ug/kg/day (the highest dose tested) since no systemic effects (other than ChE) were observed. This study, when taken into consideration with the 4-week dog plasma ChE study (described below), satisfies the requirement for a chronic toxicity study in a nonrodent species. The NOEL for brain/RBC ChE in this study is 60 ug/kg/day.

4. ChE Inhibition

A special 4-week ChE study was conducted in dogs to define the dose-response of terbufos for plasma ChE. In this study, male and female dogs were administered terbufos in capsule form at dose levels of 0, 1.25, 2.5, 5.0, or 15.0 ug/kg/day. A plasma ChE NOEL is set at 1.25 ug/kg/day.

Dose-related plasma ChE inhibition was observed at the two lower dosages of 5 and 1.25 ug/kg/day in both male and female dogs. In males, ChE activity was approximately 80 percent of control values during all sampling periods at 5 ug/kg/day with 10 to 15 percent (depending on which control values are used) inhibition at 2.5 ug/kg/day. No essential inhibition of plasma ChE occurred at the lowest dose of 1.25 ug/kg/day. A similar pattern of enzyme activity was observed in the females, with 20 to 30 percent inhibition at the 5 ug/kg/day dose level for weeks 1, 2, and 4, and 10 to 20 percent inhibition at the 2.5 ug/kg/day dose levels (again depending upon whether concurrent or pretest control values are compared). No inhibition was observed at the lowest dose tested of 1.25 ug/kg/day.

Brain and RBC ChE activities were also evaluated in this study. Terbufos did not depress RBC ChE activity in either male or female dogs at any dose or sampling time period during the study. This lack of depression upon RBC ChE is in agreement with the lack of effects at dosages of 15 ug/kg observed in the 1-year dog study described above. No compound-related effect for brain ChE activity was observed in either males or females at 15 ug/kg.

5. Metabolism

In male rats, terbufos was rapidly excreted as the diethyl phosphoric acid and other polar metabolites (83%) in urine within 168 hours of administration. Terbufos and its metabolites were not noted to accumulate in tissues.

6. Mutagenicity

The Agency has reviewed the available data and results of these studies are summarized below. No additional mutagenicity data are required.

Ames - With and without chromosomal activation, the results were negative at concentrations up to 1000 mcg per plate.

Acute in vivo Cytogenetic Assay - Terbufos did not appear to cause any chromosomal aberrations. The maximum doses tested were 1.8 mg/kg in males and 1.5 mg/kg in females (higher doses caused mortality).

Dominant Lethal - In rats, the only apparent possible compound-related effects on fertility were in the high-dose group (0.4 mg/kg) where the number of viable implants was slightly, but significantly, reduced at mating 9, and implantation efficiency was significantly lower at mating 7 as well as suggestively (not significant) lower during matings 8, 9, and 10.

7. Reproduction

The Agency evaluated a three-generation rat reproduction study utilizing dosages of 0.25 and 1.0 ppm. At the 1.0 ppm dose level, there was an increase in the percentage of litters with offspring death in each of three generations as compared with the controls. A NOEL of 0.25 ppm for reproduction effects was established for the study. No additional reproduction data are needed.

8. Developmental Toxicity

The Agency evaluated two rabbit teratology studies and one rat teratology study. The rat study in which pregnant COBS® CD female rats were orally administered technical terbufos during days 6 through 15 of gestation at dose levels of 0, 0.05, 0.10, or 0.20 mg/kg/day is acceptable for assessing the potential developmental toxicity of terbufos. In this study, the maternal toxicity NOEL was established at > 0.2 mg/kg (HDT). There was an increase (not statistically different) in the number of early resorptions and the number of litters with two or more resorptions at 0.1 and 0.2 mg/kg, and increased postimplantation loss at 0.2 mg/kg. The developmental toxicity NOEL was conservatively established at 0.1 mg/kg and the LEL at 0.2 mg/kg. Of the two available rabbit studies, one was considered invalid due to the uncertainty as to the actual dose levels or test material administered to the rabbits during the test period. The other study was considered unacceptable due to inadequate numbers of litters, excessive maternal wastage, low insemination rate and/or implantation efficiency, high variation in reported doses administered, and questions due to apparent gavage errors. A new rabbit teratology study is required.

9. Occupational Exposure Risk

Limited field worker exposure data were gathered in a study utilizing aerial application of 1.0 lb ai terbufos per acre to corn in Nebraska. Since the dermal exposure data collected during this study are not acceptable, primarily due to the methodology used for assessing hand exposure, the foliar dislodgeable residue levels (FDRs) on corn were used to calculate the predicted levels of dermal exposure. The FDRs were used in combination with surrogate data to give estimated dermal exposure levels of 118 ug/hour on 3 days after application and 73 ug/hour on 7 days after application. Utilizing an oral 4-week ChE inhibition study in dogs with a ChE NOEL of 0.00125 mg/kg, and a safety factor of 10, the calculated allowable exposure level for humans is estimated to be 1.22 mg/hr for a 60 kg. person. Since exposure to fieldworkers would be primarily by the dermal route, a dermal toxicity study in test animals would be more appropriate for the calculation of allowable human exposure levels and a special 21-day dermal study in rats to establish a NOEL for ChE inhibition is being requested for this purpose.

Environmental conditions, especially rainfall, humidity, and dew have a strong influence on the rate of dissipation of organophosphorous pesticides such as terbufos. It is expected that a broadcast application without soil incorporation of terbufos in an arid environment such as the Southwestern States would result in greater exposure to fieldworkers in those States. A dislodgeable residue study to be conducted in New Mexico is therefore needed to estimate fieldworker exposure in the arid Southwest resulting from aerial or broadcast application to corn. At present, New Mexico is the only Southwestern State in which such a use of terbufos is registered.

The required protective clothing for workers reentering corn fields within 7 days of broadcast application without soil incorporation and the prohibition of nonsoil-incorporated terbufos application prior to detasseling activities imposed in this Registration Standard would mitigate adverse effects to workers reentering the treated areas pending submittal and evaluation of the special dermal study and the dislodgeable residue study described above.

There is little potential for worker reentry exposure in fields treated with a ground-incorporated application of terbufos. Consequently, no reentry data or reentry interval are required to support these uses.

C. Environmental Profile

1. Ecological Effects

a. Terrestrial Species

Based on acceptable laboratory data, technical terbufos is highly toxic to upland game birds on an acute oral basis with a single-dose oral toxicity value of 28.6 mg/kg. Based on two acceptable subacute dietary studies in birds, technical terbufos is highly toxic to upland game birds with subacute toxicity values of 143 and 157 ppm.

Two acceptable avian reproduction studies were reviewed - one conducted with the bobwhite quail, the other with the mallard duck. The quail study showed no reproductive effects at concentrations up to 30 ppm in the diet. In the mallard duck study, there were no apparent effects at 1 and 5 ppm but there was a slight reduction in embryo viability at 15 ppm. This effect was not considered to be statistically significant.

Terrestrial organisms may be exposed to terbufos directly through ingestion of granules at or near the soil surface. Based on a granular weight of 0.1 mg, it is calculated that it would take 27 granules of a 15 percent terbufos product to reach the acute oral toxicity of a small bird such as a field sparrow with a weight of 0.0139 kg, if such a bird had the same sensitivity to terbufos as the bobwhite quail. However, in the available toxicity screening studies it was found that 10 granules killed all five redwinged blackbirds given this dose and killed two of the five house sparrows receiving this dose. A dose of 20 granules killed four of the five blackbirds receiving this dose. None of the blackbirds receiving dosages of 1 and 5 granules were killed. These results suggest that an approximate median lethal dose (the dose that can be expected to cause death in 50% of the test animals) for the redwinged blackbird is likely to be greater than 5 (0.075 mg terbufos), but less than 10 granules (0.15 mg terbufos) of the 15 percent terbufos product. With 0.07 kg as the bodyweight of the blackbird, the calculated median lethal dose would be between 1.1 and 2.1 mg ai/kg bodyweight. This would be 13 times the median lethal dose of 28.6 mg/kg found in the previously mentioned bobwhite quail acute oral toxicity study in which technical terbufos was used as the test substance. Since only granules were tested in the screening studies, it was not clear whether this increased toxicity was due to differences in sensitivity between the two test species or increased toxicity of the 15 percent granular formulation, or both. While results of acute oral toxicity testing using both the technical terbufos and the 15 percent granular product indicate that the 15 percent formulation is less toxic than the technical, they do not address the species sensitivity question.

Based on an acceptable level 1 terrestrial field study, a 15 percent granular formulation of terbufos caused acute mortality of terrestrial nontarget species when applied to corn fields. In this study, 2 lb ai/A applied at time of planting as a soil-incorporated treatment resulted in mortalities to birds and reptiles, while aerially broadcast unincorporated granules applied to a maturing corn crop at one-half this rate resulted in significant mammal, bird, and reptile acute mortality. No secondary poisonings were observed.

Other studies reviewed by the Agency include an additional terrestrial field study in which a 15 percent granular terbufos product was applied to corn fields at 1 lb ai/A and an outdoor pen study in which ring-necked pheasants were exposed to soil treated with the 15 percent granular product at rates equivalent to 1 and 5 lb technical terbufos/A. While results of the field study implied minimal effects on wildlife, it was not acceptable for use in a hazard assessment of terbufos. Deficiencies in the study include use of maximum application rates which were lower than the currently registered maximum rate; a limited number of searches for dead animals, and no analysis for ChE inhibition. While the results of the pen study also indicated minimal hazard to the species tested, it was deficient in that the exposure was not considered representative of the principal route of exposure under conditions of actual use which is expected to be dietary. Since clean food and water were provided at all times during the study, exposure to terbufos was principally dermal.

Based on the adverse effects observed in the acceptable level 1 study described above, the Agency is requiring population studies or level 2 terrestrial field studies to assess the potential effects on populations of birds, mammals, and reptiles and to complete its evaluation of the potential hazard to terrestrial nontarget species.

b. Aquatic Species

Based on acceptable laboratory studies, technical terbufos is very highly toxic to freshwater fish and to freshwater invertebrates on an acute basis. The acute toxicity values for freshwater fish range from 0.77 to 20.00 parts per billion (ppb). The acute toxicity for freshwater invertebrates (*Daphnia magna*) is 0.31 ppb. Technical terbufos appears to be highly toxic to marine/estuarine fish based on results of a 96-hour acute toxicity study on sheepshead minnow, and to marine/estuarine invertebrates based on results of a 96-hour acute toxicity study on mysid shrimp. These studies deviated from the recommended protocols, however, and are not adequate to completely characterize the acute toxicity of technical terbufos to either of these species. There was no information available to characterize the toxicity of technical terbufos to marine/estuarine molluscs.

The acute toxicity studies with estuarine and marine organisms are required because some of the crops (e.g., field corn and sorghum) may involve use of the chemical on more than 300,000 acres in coastal counties and because use on these crops is likely to result in runoff that may be transported to the habitats of estuarine and marine organisms.

Based on results of an aquatic invertebrate life cycle study using Daphnia magna, technical terbufos is extremely chronically toxic to freshwater aquatic invertebrates with an maximum acceptable toxicant concentration (MATC) in the parts per trillion (ppt) range based on growth, survival, and reproduction. The available information is not sufficient to completely characterize the chronic toxicity of terbufos to fish in an early life stage test. The available test, which was conducted with rainbow trout, is not acceptable because it failed to meet the requirement that at least one test level must adversely affect a life stage. This study is required because the lowest fish acute toxicity value (0.77 ppb) is well under 1 mg ai/L; results of the initial modeling show the EEC in water is greater than 0.01 of the acute toxicity; the hydrolylic half-life is greater than 4 days at 5, 7, and 9; some degradates, based on their structure, may have a toxicity similar to or greater than that of the parent compound; and due to terbufos' broad and repeated use in corn, the chemical is expected to be transported to water from the intended use site.

A Daphnia magna acute toxicity study and two 96-hour fish studies using the 15 percent granular formulation were reviewed and found acceptable. Based on the results of these studies, the formulated product is very highly toxic to bluegill sunfish, rainbow trout, and Daphnia magna with acute toxicity values of 12.3, 59.7, and 6.2 ppb, respectively.

Aquatic organisms may be exposed to terbufos through runoff of the granules or through transport of soil or water containing residues of terbufos or its degradates. This potential exposure has been demonstrated by reports of a fish kill incident. During the conduct of the previously described acceptable level 1 terrestrial field study, an aerial broadcast application to a corn field in the Chesapeake Bay region reportedly resulted in an estuarine fish kill. Based on the results of initial modeling conducted by the Agency for the 1983 Terbufos Registration Standard, aquatic EECs resulting from the soil-incorporated use of terbufos may pose an acute hazard for freshwater and marine/estuarine species. Potentially greater hazards are likely for aerial applications of terbufos granules since soil-incorporated applications typically provide less exposure than aerial broadcast applications. The Agency used a computer model to simulate runoff from granular applications of terbufos. The EECs of terbufos in the hypothetical ponds of the model ranged from 7.4 ppb on day 15, immediately after the second runoff event, and declined to

0.035 ppb by day 60. Residues sorbed to benthic sediment were 3.7 ppb on day 26 and declined to 2.1 ppb by day 60. The model was not able to consider degradates, certain of which (based on molecular structure) may be as toxic as terbufos itself. On the basis of terbufos toxicity to aquatic organisms, the EEC levels may pose an acute hazard for freshwater and marine/estaurine species. Residue levels of concern were exceeded for 38 to 56 days out of a total of 56 days following initial pesticide runoff. The potential chronic hazard to freshwater invertebrates may be even greater than the acute hazard based on results of the previously described 21-day chronic (life-cycle) study which showed Daphnia magna to be extremely sensitive to terbufos.

Although these theoretical calculations and modeling indicate that the use of terbufos may result in adverse effects to aquatic species, actual field monitoring data are not available to support this finding. Moreover, the environmental fate characteristics of terbufos are not accurately defined by available data. Thus the models can be used only on a limited basis.

Aquatic residue monitoring studies will be required to determine actual residues in aquatic systems exposed to runoff and spray drift. Although these studies were previously requested in the 1983 Terbufos Registration Standard, their initiation was delayed pending the Agency's recalculation of the EECs. Prior to the completion of this task, reports of the above described fish kill incident demonstrating the potential exposure to aquatic organisms under actual field use conditions became available. In addition, several environmental fate studies previously found acceptable do not meet current Guideline requirements and need to be repeated.

Based on new acute and chronic data as well as the reported fish kills, aquatic field studies are required to investigate the potential adverse effects to aquatic organism populations of aquatic exposures to terbufos resulting from drift and runoff of agricultural applications of the chemical. These studies should be conducted on both freshwater and marine/estuarine sites with corn as the crop.

c. Nontarget Insects

Since terbufos is registered only as a granular formulation, no significant bee exposure is expected.

d. Endangered Species

There is sufficient information to indicate that current registered uses of terbufos may adversely affect endangered species. Threshold levels of concern to aquatic endangered species (EEC > 1/20 acute toxicity value) are exceeded by terrestrial, soil-incorporated applications (due to runoff). Potentially greater hazards are likely for aerial applications of terbufos granules since soil-incorporated applications typically provide less exposure than aerial broadcast applications.

Terbufos has been identified by the Office of Endangered Species (OES), U.S. Fish and Wildlife Service (USFWS), as being likely to jeopardize the continued existence of certain endangered species when used on corn and sorghum. Based on this determination, OES specified reasonable and prudent alternatives to avoid jeopardizing the continued existence of the identified species. EPA is working with USFWS and other Federal and State agencies to implement the alternatives in a technically sound manner.

Formal consultation will be initiated with OES under Section 7 of the Endangered Species Act regarding the potential exposure to endangered species resulting from the registered use of terbufos on sugar beets.

2. Environmental Fate

Results of an acceptable hydrolysis study indicate that terbufos degrades with a half-life of 2.2 weeks. Formaldehyde was the major degradate detected in this study. Results of an acceptable aerobic soil metabolism study indicate that terbufos degrades in silt loam soil with a half-life of 26.7 days. The major degradates detected in this study included carbon dioxide, terbufos sulfoxide, and terbufos sulfone.

Results of a field dissipation study, classified as supplementary, indicate that terbufos residues have a half-life of less than 40 days in field plots of loam soil located near Arcola, Illinois, and sandy loam soil located near Greeley, Colorado treated with a 15 percent granular formulation at an application rate of 1 lb ai/A. The sampling protocol was inadequate to accurately assess the dissipation of terbufos residues in field soil and a new study is required.

The available data reviewed by the Agency are not sufficient to fulfill data requirements nor to assess the environmental fate of terbufos. Four studies previously reviewed and found acceptable under the 1983 Terbufos Registration Standard do not meet the requirements of the Agency's current guidelines and new studies are required. These are: anaerobic soil metabolism, leaching, fish accumulation, and field dissipation. In addition, several new studies are now required due to the additional method broadcast (air or ground equipment) application without soil incorporation which was not registered at the time of the 1983 Terbufos Registration Standard.

Based on an inadequate data base, no definitive conclusions can be made about the potential for terbufos to leach to ground water. Terbufos residues were reported to occur in well-water sampling in Iowa and Minnesota. These reports, however have not been confirmed in the laboratory and a resampling of the same Iowa wells a year later, in 1986, showed no detections for terbufos or its degradates. The earlier report of the Minnesota well detection has been attributed to a point source and not to normal agricultural application. Because terbufos is so susceptible to hydrolysis, there is some question about any laboratory's ability to detect it or confirm a detection. Terbufos has been identified as an unstable analyte in the National Well Water Survey. Additional data are required to assess the mobility and leaching characteristics of terbufos and its degradates. These data include leaching and soil dissipation studies.

No ground water monitoring studies are required at this time. Pending receipt and evaluation of more complete environmental fate information, ground water monitoring studies may be required in the future.

D. Pesticide Incident Reports

Data on occupational illness due to pesticide exposure have been received from California, which requires that all such physician-treated illnesses be reported to the State. There were no physician-treated cases of terbufos poisoning from 1980 through 1986. During this same period, there were no reported hospitalized cases of occupational terbufos poisoning. Based on a 12 percent sample of the nation's hospitals, there were no observed cases of hospitalization due to terbufos exposure during the time period from 1971 through 1976. The Terbufos Registration Standard issued in 1983 included information obtained from the Pesticide Incident Monitoring System (PIMS), which was utilized by the Agency prior to 1982, and which showed 31 reports involving terbufos. The Agency concluded, as was stated in the 1983 Terbufos Registration Standard, that carelessness and/or negligence appear to have been important factors in most instances, and that strict adherence to proper storage and application techniques as prescribed in the label directions and precautions will minimize the risk of potential adverse effects to humans and domestic animals.

E. Tolerance Reassessment

1. Tolerances Issued

Tolerances have been established for combined residues of terbufos and its ChE-inhibiting metabolites in or on the raw agricultural commodities bananas, sugar beets, corn, and sorghum (40 CFR 180.352). No food additive tolerances have been established for terbufos. Canadian tolerances exist on a negligible residue basis (at less than 0.1 ppm in human food) for sugar beets and corn. There are no Mexican tolerances and no Codex maximum residue limits (MRLs) set for terbufos. Therefore, no compatibility questions exist with respect to the Codex MRL.

The tolerance on bananas expires on April 27, 1990 because of the lack of a teratology study in a second species. Should the Agency find that the new rabbit teratology study is acceptable, it will reassess the tolerance for bananas and, if appropriate, will establish a permanent tolerance for this commodity.

The established tolerances for terbufos are presently expressed in terms of terbufos and its ChE-inhibiting metabolites without specifying the latter as phosphorylated metabolites. The Agency will propose revising 40 CFR 180.352 by changing the wording to read:

"...terbufos... and its phosphorylated (cholinesterase-inhibiting) metabolites:

- Phosphorothioic acid, S-(t-butyl-thio) methyl O,O-diethyl ester.
- Phosphorothioic acid, S-(t-butyl-sulfinyl) methyl O,O-diethyl ester.
- Phosphorothioic acid, S-(t-butyl-sulfonyl) methyl O,O-diethyl ester.
- Phosphorodithioic acid, S-(t-butyl-sulfinyl) methyl O,O-diethyl ester.
- Phosphorodithioic acid, S-(t-butyl-sulfonyl) methyl O,O-diethyl ester."

The Agency will also propose that the "(N)" designation be deleted from the sugar beet roots, corn grain, and sweet corn entries under 40 CFR 180.352. This designation indicates that the preceding tolerance level was set at the level of detection or on a negligible residue basis. Tolerances are no longer established on a negligible basis, and such designations are being systematically removed from 40 CFR 180.

Because of the residue chemistry data gaps, the Agency cannot conduct a tolerance reassessment until the required data are submitted and reviewed.

2. Residue Data

In the Terbufos Registration Standard dated June 1983, no outstanding data gaps were identified for residue chemistry. However, subsequent amendments to registered uses for terbufos and addenda to the Pesticide Assessment Guidelines (Subdivision O) for Residue Chemistry have made it necessary to reevaluate portions of the data base previously reviewed under the June 1983 Standard. As a result, some of the original conclusions regarding adequacy of the data and support for tolerances have been modified in this revised Registration Standard.

a. Metabolism

Based on an evaluation of the available plant metabolism studies, the Agency concludes that the nature of residues in plants is adequately understood. The major portion (70 to 90%) of the organosoluble ^{14}C-residues present in the treated plant tissues was characterized. Of the phosphorylated metabolites, terbufoxon sulfoxide and terbufos sulfoxide comprised $\leq$ 30 percent of the residues; and terbufos sulfone and terbufoxon sulfone comprised $\leq$ 7 percent of the residues. The major nonphosphorylated metabolite which comprised $\leq$ 30 percent of the organosoluble ^{14}C-residues was nonphosphorylated terbufoxon sulfone and the minor ones which comprised $\leq$ 13 percent were nonphosphorylated terbofoxon sulfoxide, methane (t-butysulfonyl)(t-butylsulfonyl) and methane (t-butylsulfinyl) (methylsulfinyl).

The available poultry and ruminant feeding studies do not meet the current Guideline requirements for data depicting the metabolism of terbufos in livestock. The studies were not conducted with radiolabeled material nor were the animals dosed at a level high enough for detection of residues in the animal tissues and milk. The available rat metabolism study conducted with radiolabeled terbufos indicates that residues were rapidly excreted. Fifty percent of the total amount excreted during the study was excreted at the end of 15 hours. Less than 0.1 ppm remained in each tissue at the termination of the study. The major metabolites consisted of S-methylated series of metabolites. Should the requested ruminant and poultry metabolism studies reveal that the metabolism of terbufos in these animals differs from that in rats, then a swine metabolism study would be required.

b. Analytical Methodology

An adequate analytical method, published as method I in PAM, Vol. II, is available for the collection of data pertaining to the combined residues of terbufos and its ChE-inhibiting metabolites in or on sugar beet tops and roots; corn forage and grain; and sorghum. Because the nature of the residues in animals is not adequately understood, no conclusions can be made regarding the adequacy of the available methods for detection of terbufos residues of concern in animal products. Upon receipt of the required animal metabolism studies, the adequacy of the available methods for detection of terbufos residues of concern in animal products will be evaluated. Adequate methodology and validation data for each of the metabolites identified in the plant metabolism studies are available for only a few commodities. Validation data pertaining to recovery of the individual metabolites listed in the revised tolerance expression proposed by the Agency, are required for additional representative plant commodities. Terbufos residues are detected by the Food and Drug Administration (FDA)-U.S. Department of Agriculture (USDA) multiresidue Protocols II and III. Additional testing is needed by multiresidue Protocol IV. In addition, each of the phosphorylated metabolites must be tested by all four FDA-USDA multiresidue protocols.

c. Residue Storage Stability

Available storage stability data indicate that residues of terbufos and its metabolites are stable in corn grain and corn forage stored frozen for up to 5 months. No data are available depicting the stability of these residues in or on other plant commodities and these data are required. In addition, data are required depicting the storage stability of each separate metabolite listed in the revised tolerance expression proposed by the Agency. The need for storage stability data pertaining to terbufos residues of concern in animal tissues will be addressed upon receipt and evaluation of the required animal metabolism studies.

d. Field Residue Data

The available data on the magnitude and levels of residue of terbufos in the individual raw agricultural commodities are not adequate to determine the adequacy of the established tolerances on sugar beets, corn, and sorghum and additional data are required.

e. Processing Data

Data are available to demonstrate that terbufos residues will not concentrate in sugar beet processed commodities. Processing studies are lacking for corn and sorghum and are required.

f. Meat, Milk, Poultry, and Eggs

The available poultry and ruminant feeding studies, described in the metabolism section, show that no detectable residues occur in eggs, chicken tissues, milk, or cattle tissues from animals fed exaggerated dietary levels of terbufos and its ChE-inhibiting metabolites. However, additional animal metabolism data are required and a determination regarding the need for and nature of tolerances for residues in meat, milk, poultry, and eggs will be made upon receipt and evaluation of these data.

g. FDA Monitoring and Surveillance

The FDA Revised Total Diet studies, as well as the Surveillance and Compliance program for domestic and imported commodities, employ methodology which is known to determine terbufos. No findings of terbufos were reported in Total Diet study samples collected from April 1982 to April 1986. A total of 234 Total Diet food items were analyzed. Information obtained from FDA's Surveillance and Compliance program for samples collected from the 1978 fiscal year to the 1987 fiscal year indicate that a limited number of samples of various commodities were found to contain residues of terbufos. Tolerance-exceeding residues of terbufos were observed in field corn silage (1.16 ppm, 1.10 ppm). Residues of terbufos were observed in the following domestic commodities for which no tolerances exist: meat (0.007 ppm, 0.14 ppm) and meal feed product (200 ppm); animal fat (from a trace to 0.44 ppm) and bone meal (from a trace to 0.08 ppm); chicken fat (0.27 ppm) and meat and bone meal (trace); and spent malt barley (trace). One imported commodity, chaom, was found to contain 0.04 ppm. A total of 100,824 samples were analyzed.

3. Reference Dose (RfD)

Due to the lack of pertinent data, an RfD for terbufos residues could not be established when the Terbufos Registration Standard was issued in 1983.

Data lacking for the chronic feeding, oncogenicity, and teratology data requirements have been received and evaluated. With the exception of the rabbit teratology study, which was found to be supplemental as described under Section III A.1. of this document, they are acceptable for use in determining an RfD.

Based on the plasma ChE inhibition NOEL as defined in a 4-week dog study (0.00125 mg/kg/day) and using a safety factor of 10, the RfD for humans is 0.000125 mg/kg/day.

The current established tolerances for residues of terbufos and its ChE-inhibiting metabolites result in a TMRC of 0.000052 mg/kg/day and utilize 41.946 percent of the RfD. This value utilizes the residue values of the published tolerances and assumes that 100 percent of the crops were treated with terbufos.

IV. REGULATORY POSITIONS AND RATIONALES

A. Regulatory Positions

1. The Agency is not placing terbufos into Special Review at this time. Additional data are needed to complete the Agency's risk assessment to aquatic and avian species, including endangered species. The Agency is conducting a comparative avian risk assessment of various granular pesticides including terbufos. When this assessment is completed, further regulatory action may be taken.

Rationale: Based on a high acute toxicity of terbufos to avian species and the current registered uses of terbufos, there exists a high potential for adverse effects to avian species from exposure to terbufos granules at or near the soil surface. This potential for exposure to terbufos is demonstrated from results of level 1 studies and is confirmed by bird kill incidents. The Agency is currently evaluating these data in the context of a comparative risk assessment of granular pesticides which may pose a risk to birds. When this assessment is completed, the Agency will determine whether further regulatory action is necessary.

Theoretical calculations indicate that the predicted concentrations of terbufos in the aquatic environment resulting from the registered uses of terbufos might expose aquatic species to residue levels exceeding risk criteria for Special Review. These calculations, however, are based upon models and may not be indicative of actual residue levels in aquatic sites. Upon receipt and evaluation of the full-scale aquatic organism field study and the aquatic residue monitoring data, a determination will be made regarding further regulatory action.

2. A level II terrestrial field study, monitoring studies in soil, water, sediment, and fish, and an aquatic organism field study are required to support the continued registration of terbufos.

Rationale: These studies are needed for the completion of the Agency's assessment of the potential risk to both avian and aquatic species resulting from registered uses of terbufos. Refer to Section C.3. in Chapter III of this document for a discussion of the potential risks based on available data.

3. The Office of Endangered Species (OES) in the U.S. Fish and Wildlife Service (USFWS) has determined that certain uses of terbufos, including uses on corn and sorghum, may jeopardize the continued existence of endangered species. EPA is developing a program to reduce or eliminate exposure to these species to a point where use does not result in jeopardy, and will issue notice of any necessary labeling revisions when the program is developed. No additional labeling is required at this time. Labeling requirements issued in PR Notices 87-4 and 87-5 have been withdrawn pending reissuance.

In addition, the Agency is seeking OES evaluation of the additional use of terbufos on sugar beets.

Rationale: Technical terbufos is potentially highly toxic to birds, fish, aquatic invertebrates, mammals, and reptiles.

In May 1987, EPA issued PR Notices 87-4 and 87-5 in response to OES findings that certain pesticides, including terbufos, jeopardized the continued existence of endangered species. Those PR Notices directed registrants to add labeling to their products which referred users to additional information that, in turn, explained limitations on use of terbufos within the range of jeopardized endangered species.

Subsequent to issuance of these PR Notices, EPA identified a number of significant technical errors and inconsistencies in the information to which users would have been referred. Therefore, on January 26, 1988, the Agency issued

PR Notice 88-1, which withdrew PR Notices 87-4 and 87-5 pending development of a more focused program to protect endangered species. EPA is working to correct these errors prior to requiring labeling to protect endangered species. When that program is fully developed, notice of any labeling necessary to protect endangered species will be issued.

4. The Agency is imposing a 7-day reentry interval on an interim basis pending submittal and evaluation of the required reentry data and the special 21-day dermal study. This reentry labeling restriction is being imposed for the use of terbufos on corn as an aerial application and as a broadcast (without soil incorporation) application.

Rationale: Current data are not adequate to establish a definitive reentry interval. Establishment of an interim reentry interval is based on the high acute toxicity properties of technical grade terbufos and the high likelihood of exposure to terbufos residues of workers who perform activities in the treated site specified above. Refer to Section B.9. in Chapter III of this document for a discussion of the available reentry data and an assessment of the occupational exposure risk.

5. The Agency is imposing additional worker safety and protective clothing statements for EPs containing terbufos.

Rationale: Though the Agency has had no recent reports of terbufos poisoning incidents, it is concerned that exposure could present a health risk to agricultural workers due to the high acute toxicity of terbufos. These additional protective measures are being imposed to minimize this exposure.

6. The Agency is imposing a restriction against use of terbufos as an aerial or broadcast application on seed corn prior to any detasseling operations.

Rationale: This restriction is based on the high acute toxicity properties of technical grade terbufos and the high likelihood of exposure to terbufos residue of workers who perform detasseling activities in seed corn fields treated with an aerial or broadcast (without incorporation) application of terbufos.

7. A special 21-day dermal study in rats is required to support the continued registration of terbufos as an aerial or broadcast application on corn.

Rationale: This study is needed for the completion of the Agency's assessment of the potential risk to field workers reentering fields following aerial or broadcast treatment without soil incorporation with terbufos. Refer to Section B.8. in Chapter III of this document for a discussion of the potential risks based on available data.

8. The Agency is deferring decisions concerning terbufos' potential for contaminating ground water until information on the environmental characteristics and fate have been submitted and reviewed.

Rationale: The Agency is unable to complete its assessment of the potential for terbufos to contaminate ground water because the mobility characteristics of this chemical are largely unknown. Soil column leaching and field dissipation data are incomplete and additional data are required. The limited data available appear to indicate that under most environmental conditions terbufos would be unlikely to leach to ground water in measurable quantities. The available data indicate that terbufos is not hydrolytically persistent with a half-life of 2.2 weeks.

9. In order to meet the statutory standard for continued registration, the Agency has determined that terbufos products must bear revised and updated fish and wildlife toxicity warnings. Specific wording is given in Section IV.D.

Rationale: Available data indicate that terbufos is highly toxic to birds, fish, aquatic invertebrates, small mammals, and reptiles.

10. The Agency is retaining the Restricted Use classification for the currently registered 15 percent granular product.

Rationale: The Restricted Use classification was imposed under the 1983 Terbufos Registration Standard, as amended on February 27, 1985, based on the high acute oral and dermal toxicity to humans. There is no scientific basis for changing the classification of terbufos.

11. The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible.

The following studies have been identified to receive priority review either as soon as they are received by the Agency or as otherwise indicated below:

Data and When Reviewed	Reason
Toxicology	
Special 21-day Dermal Study in Rats	Assessment of reentry risk

Data and When Reviewed	Reason
83-3 Rabbit Teratology	Tolerance assessment
Environmental Fate/Exposure (Upon receipt of all five studies)	
161-2 Photodegradation in Water	Assess leaching potential
161-3 Photodegradation in Soil	Assess leaching potential
162-2 Anaerobic Soil Metabolism	Assess leaching potential
163-1 Leaching	Assess leaching potential
164-1 Soil Dissipation	Assess leaching potential
165-2 Volatility (lab)	Tier study
Reentry Protection	
132-1 Foliar Dislodgeable Residue Dissipation in New Mexico	Assessment of reentry exposure
Residue Data	
171-4 Animal Metabolism in Ruminants and Poultry	Tiered study
Wildlife and Aquatic Organisms	
71-5 Field Testing - Mammals and Birds	Avian risk concern
72-3 Acute Toxicity to Estuarine and Marine Mammals (upon receipt of both 72-3 and 72-4)	Tier study
72-4 Fish Early Life Stage	Tier study
72-7 Field Testing-Aquatic Organisms	Aquatic organism risk concern

12. While data gaps are being filled, currently registered MPs and EPs containing terbufos may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Even when authorized under FIFRA sections 3(c)(2)(B) and 3(c)(7) the Agency may elect not to cancel or withhold registration though data are missing or are inadequate. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

B. Criteria for Registration

To be registered or reregistered under this Standard, products must contain terbufos, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. Acceptable Ranges and Limits

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain terbufos. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing terbufos provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed below. The EPA Index to Pesticide Chemicals lists all registered uses, as well as approved maximum application rates and frequencies.

-Terrestrial, non-domestic, food uses on:

corn; grain sorghum; and sugar beets.

D. Labeling

In order to remain in compliance with FIFRA, products must bear appropriate labeling as specified in 40 CFR 156.10 and this Standard, or must be revised to conform to those specifications. Appendix II contains information on label requirements.

No pesticide product containing terbufos may be released for shipment by the registrant after November, 1989, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing terbufos may be distributed or sold after November, 1990 unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA:

1. Ingredients Statement

The ingredient statement for products must list the active ingredient as:

Terbufos: S-[[(1,1-dimethylethyl)thio]methyl] O,O-diethyl phosphorodithioate __________%

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

Labels for MPs must bear the following identifying phrase directly beneath the product name:

> "An insecticide and nematicide for formulating use only."

In the directions for use, the following statement regarding acceptable use patterns must appear on MP labels:

> "For formulation into end-use insecticide and nematicide products intended only for (list acceptable sites)."
>
> NOTE: No use may be included on the label where the registrant fails to agree to comply with the data requirements for that use pattern. Refer to Section B; Use Profile in Chapter II for the acceptable sites.

3. Precautionary Statements

Statements for Manufacturing-Use Products

a. The following fish and wildlife statements are required to appear under the "Environmental Hazards" heading:

This pesticide is extremely toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollution Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or the Regional Office of EPA.

Statements for End-Use Products

a. The following work safety rules and protective clothing statments must appear on the label of end use products:

WORK SAFETY RULES

REPEATED EXPOSURES TO CHOLINESTERASE INHIBITORS SUCH AS ARE CONTAINED IN THIS PRODUCT MAY, WITHOUT WARNING, CAUSE PROLONGED SENSITIVITY TO VERY SMALL DOSES OF ANY CHOLINESTERASE INHIBITOR.

Persons working with this product should have frequent blood tests of their cholinesterase levels. If the cholinesterase level falls below a critical point, no further exposure should be allowed until it has been determined by means of blood tests that the cholinesterase level has returned to normal. Before using this product, consult the National Pesticide Telecommunication Network for recommendations regarding such blood tests, poisoning management, emergency treatment, and other information regarding the toxicity of terbufos. The toll-free number for the National Pesticide Telecommunication Network is 1-800-858-7378.

If handled indoors, provide mechanical exhaust ventilation.

Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is danger of drift.

Do not rub eyes or mouth with hands. If you feel sick in any way, STOP work and get help right away. See First Aid (Practical Treatment) section.

WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING LOADING, APPLICATION, EQUIPMENT REPAIR, EQUIPMENT CLEANING, AND DISPOSAL OF THE PESTICIDE.

Wear a protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet. Wear chemical-resistant gloves and chemical-resistant shoes, shoe coverings, or boots. Wear goggles and a pesticide respirator approved by the National Institute for Occupational Safety and Health (NIOSH) and the Mine Safety and Health Administration (MSHA) at all times except during application.

If application is performed using an enclosed cab or cockpit, the following protective clothing may be worn as an alternate: long-sleeved shirt and long-legged pants; shoes and socks. Chemical resistant gloves must be available in the cab or cockpit and must be worn while exiting. All other protective clothing required for use during application must be available in the cab and must be worn when exiting the cab into treated areas.

IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before smoking, drinking, or toileting.

IMMEDIATELY AFTER COMPLETING WORK WITH THE PESTICIDE, take off all clothing and shoes. Shower using soap and water. Do not reclothe with contaminated clothing and shoes. Wash protective clothing and protective equipment with soap and water after each use. Respirators must be cleaned and filters replaced according to instructions included with the respirators. Personal clothing worn during use must be laundered separately from household articles. Clothing and protective equipment heavily contaminated with terbufos must be destroyed according to State and local regulations. HEAVILY CONTAMINATED CLOTHING (CLOTHING ON WHICH THE PRODUCT HAS SPILLED) CANNOT BE ADEQUATELY DECONTAMINATED.

DURING AERIAL APPLICATION, HUMAN FLAGGERS ARE PROHIBITED UNLESS IN A TOTALLY ENCLOSED VEHICLE.

b. The following reentry statement and worker protective clothing statements must appear on all products intended for aerial application or broadcast application to corn:

"Reentry into treated areas is prohibited for 7 days after the end of application unless the protective clothing specified on this label for early reentry is worn."

"FOR EARLY REENTRY INTO TREATED AREAS: Use protective suit of one or two pieces covering all parts of the body except head, hands, and feet; chemical-resistant gloves and chemical-resistant shoes, shoe coverings, or boots."

c. The following restriction must appear on products intended for aerial or broadcast treatment for corn seed crops:

"Do not use prior to any detasseling operations."

d. The following environmental hazards statements must appear on all end-use products:

"This pesticide is extremely toxic to fish and wildlife. Birds, and mammals utilizing treated fields may be killed."

"Do not apply directly to water or wetlands (including swamps, marshes, bogs, and potholes). Runoff and drift from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Do not contaminate water when disposing of equipment washwaters. Cover or incorporate granules that are spilled during mixing and loading."

6. The following statement must appear on all end-use products containing terbufos"

"Not for use or storage in or around the home."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

---

[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by an end use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption[3], the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

---

[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to the data requirements in Table A.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

---

[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will

submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: [TERBUFOS] Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately

notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

> Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.
>
> Table B contains product-specific data requirements that apply only to a manufacturing use product.
>
> Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor
N/A= There are no registered use patterns for which the data requirement applies.

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used

to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column t requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A
Generic Data Requirements for Terbufos

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation2/	Must Additional Data Be Submitted?	Timeframe for Submission3/
§158.190 Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	Partial	00147534	Yes4/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	No	--	Yes5/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis of Product Samples	TGAI	All	No	--	Yes6/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	No	--	Yes7/	6 Months
63-3 - Physical State	TGAI	All	No	--	Yes7/	6 Months
63-4 - Odor	TGAI	All	No	--	Yes7/	6 Months
63-5 - Melting Point	TGAI	All	N/A		No8/	
63-6 - Boiling Point	TGAI	All	Yes	00142295 00147534	No	

Table A
Generic Data Requirements for Terbufos (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation2/	Must Additional Data Be Submitted?	Timeframe for Submission3/
§158.190 Product Chemistry						
Physical and Chemical Characteristics (cont'd)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	No	--	Yes7/	6 Months
63-8 - Solubility	TGAI or PAI	All	Yes	00142295	No	
63-9 - Vapor Pressure	PAI	All	Yes	00142295	No	
63-10 - Dissociation Constant	PAI	All	No	--	No9/	
63-11 - Octanol/Water Partition Coefficient	PAI	All	Yes	00142295	No	
63-12 - pH	TGAI	All	Partial	00142295	Yes7/,10/	6 Months
63-13 - Stability	TGAI	All	No	--	Yes7/	6 Months
Other Requirements						
64-1 - Submittal of Samples	N/A					

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable. However, data submitted for the technical terbufos, registered under EPA Registration No. 241-241 in response to the requests made in the Terbufos Registration Standard dated June 1983, have been evaluated with regard to their adequacy in meeting the requirements of 40 CFR 158.120.

Table A
Generic Data Requirements for Terbufos (cont'd)

§158.190 Product Chemistry Footnotes (cont'd)

2/ These data citations pertain to the technical terbufos currently registered under EPA Registration No. 241-241 and may not be applicable to technical material which differs from that described herein.

3/ Due dates refer to the number of months following the issuance of this Registration Standard, unless otherwise indicated.

4/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

5/ A detailed discussion must be submitted of all toxicologically significant impurities and all other impurities that are or may be present at ≥ 0.1% by weight, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production.

6/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

7/ Physicochemical characteristics (color, physical state, odor, specific gravity, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

8/ Not applicable; technical product is a liquid at room temperature.

9/ Not applicable to the terbufos technical product.

10/ Required if the test substance is dispersible with water.

Table A
Generic Data Requirements for Terbufos

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission1/
§158.240 Residue Chemistry					
171-2 - Chemical Identity2/					
171-3 - Directions for Use		(See Index)			
171-4 - Nature of the Residue (Metabolism) - Plants	PAIRA	Yes	00036123,00062871, 00069512,00079429, 00087686,00087688, 00087689,00087691, 00087692,00088210, 00131237,00133299	No	
171-4 - Nature of the Residue (Metabolism) - Animals	PAIRA and plant metabolites				
a. Rats		Yes	00087695	No	
b. Ruminants		Partially	00032636,00036241	Yes3/	18 Months
c. Poultry		No		Yes3/	18 Months
d. Swine		No		Reserved4/	
171-4 - Residue Analytical Methods	TGAI and metabolites	Partially	00036123,00036127, 00036129,00032646, 00036241,00036242, 00036246,00042020, 00042022,00049235, 00062872,00079431, 00087687,00087702, 00087704,00087724, 00088211,00129173, 00133299,00158614,	Yes5/	15 Months

Table A
Generic Data Requirements for Terbufos (cont'd)

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.240 Residue Chemistry					
171-4 - Storage Stability Data	TEP and metabolites	Partially	00042021	Yes[6]	15 Months
171-4 - Magnitude of the Residue Crop Field Trials					
- Root and Tuber Vegetables Group					
- Sugar Beet Roots	TEP	Partially	00036124,00036123, 00036129	Yes[7]	18 Months
- Leaves of Root and Tuber Tuber Vegetables Group					
- Sugar Beet Tops	TEP	Partially	00036124	Yes[8]	18 Months
- Cereal Grains Group					
- Corn	TEP	Partially	00039018,00042017, 00042019,00087722, 00137582,GS0109001	Yes[9,10,11]	18 Months
- Corn (processed)	TEP	No	--	Yes[12]	24 Months
- Sorghum	TEP	Partially	00079430	Yes[13]	18 Months
- Sorghum (processed)	TEP	No	--	Yes[14]	24 Months

Table A
Generic Data Requirements for Terbufos (cont'd)

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission1/
§158.240 Residue Chemistry					
171-4 - Magnitude of the Residue Crop Field Trials (cont'd)					
- Forage, Fodder, and Straw of Cereal Grains Group					
- Corn	TEP	Partially	00039018,00042017, 00042019,00087722, 00137582,GS0109001	Yes15,16/	18 Months
- Sorghum	TEP	Partially	00079430	Yes17/	18 Months
171-4 - Magnitude of Residue in Meat/Milk/Poultry/Eggs		Partially	00032636,00036241, 00087702	Reserved18/	

1/ Due dates refer to the number of months following issuance of this Registration Standard unless otherwise indicated.

2/ The same chemical identity data are required as under §158.120, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

3/ Metabolism studies using ruminants and poultry must be submitted. Animals must be dosed for at least 3 days with methylene-labeled [^{14}C]terbufos at a level high enough to permit identification and quantification of ^{14}C-residues. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in milk, eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using enforcement methods (including all FDA Multiresidue Protocols [I-IV]) to ascertain that the methods are capable of adequately recovering and quantifying all residues of toxicological concern.

4/ Data depicting the nature of terbufos residues in swine are also required if the required metabolism studies with ruminants and poultry reveal that the metabolism of terbufos in these animals differs from that in rats.

Table A
Generic Data Requirements for Terbufos (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

5/ Residues of terbufos must be tested in representative plant commodities by multiresidue protocol IV (available from NTIS under Order No. PB 86203734/AS). Also, each of the phosphorylated metabolites listed in the proposed tolerance definition must be tested by all four multiresidue protocols. In addition, methodology validation data pertaining to recovery of these individual metabolites from additional representative plant commodities are required. Additional analytical data for detection of terbufos residues of concern in animal products may be necessary upon receipt and evaluation of the animal metabolism data as described in footnotes three and four of this table.

6/ Data depicting the stability of terbufos residues of concern in or on sugar beet roots and sugar beet tops are required. Samples bearing field-weathered residues or fortified samples must be analyzed immediately after harvest or fortification and again after storage intervals that are equivalent to those reflected in all previously submitted and currently requested residue data. Storage conditions for the samples must also reflect previously submitted and currently requested data. The chosen storage intervals must allow for unforeseen delays in sample analysis. Data depicting the storage stability of each separate metabolite as listed in the proposed tolerance definition are required. Upon receipt of the requested animal metabolism data, the need for storage stability data pertaining to terbufos residue of concern in animal tissues will be addressed.

7/ The registrant must propose an appropriate tolerance for residues of terbufos and its cholinesterase-inhibiting metabolites in or on sugar beet roots based on data reflecting residues of terbufos in or on sugar beet roots harvested at normal crop maturity following at-planting application of the 15% G formulation at 4.4 lb ai/field A (2.7 oz ai/1000 ft of row, 20-inch row spacing) drilled in 2 inches to the side and 2 to 4 inches below the seed. Tests must be conducted in CA(23%), MN(20%) or ND(10%), ID(15%), and NE(7%) or CO(4%) or WY(3%) representing ca. 80% of 1985 U.S. sugar beet production (Agricultural Statistics 1986, p. 76). The registrant must propose label amendments establishing a PHI for the postemergence banded application; this PHI must be reflected by the residue data submitted.

8/ The registrant must propose an appropriate tolerance for residues of terbufos and its cholinesterase-inhibiting metabolites in or on sugar beet tops based on data depicting residues in or on sugar beet tops harvested at regular intervals through normal crop maturity following at-planting application of the 15% G formulation at 4.4 lb ai/field A (2.7 oz ai/1000 ft of row, 20-inch row spacing) drilled in 2 inches to the side and 2 to 4 inches below the seed. Tests must be conducted in CA(23%), MN(20%) or ND(10%), ID(15%), and NE(7%) or CO(4%) or WY(3%) representing ca. 80% of 1985 U.S. sugar beet production (Agricultural Statistics 1986, p. 76). The registrant must propose label amendments establishing a PHI; this PHI must be reflected in the data requested above and in all other data used to support the tolerance.

Table A
Generic Data Requirements for Terbufos (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

9/ Data are required depicting terbufos residues of concern in or on grain from field corn planted in 30-inch rows and harvested at normal crop maturity following application of the 15% G formulation in a band at-planting at 1.2 oz ai/1000 ft of row and incorporated postemergence in a band at 2.4 oz ai/1000 ft of row (3.9 lb ai/field A seasonal use rate). Tests must be conducted in IL(17%) or IA(19%), IN(9%) or MI(3%) or OH(6%), MN(8%) or WI(4%), and NE(11%) or KS(2%) collectively representing ca. 80% of 1985 U.S. corn production (Agricultural Statistics, 1986, p. 32).

10/ Data are required depicting terbufos residues of concern in or on grain of field corn grown in 30-inch rows and harvested 45 days after the last of three applications of the 15% G formulation, including a banded application at-planting of 1.2 oz ai/1000 ft of row, a postemergence banded application at cultivation at 1.2 oz ai/1000 ft of row, and a postemergence broadcast application of 1 lb ai/A applied by aerial or ground equipment (seasonal use rate of 3.6 lb ai/field A). Tests must be conducted in IA, NE, and NM, the States having SLN registrations that allow the postemergence broadcast applications. Alternatively, the registrant may elect to cancel the SLN registrations for postemergence broadcast use on field corn.

11/ Data are required depicting terbufos residues of concern in or on K+CWHR from sweet corn planted in 30-inch rows and harvested at the PHI following the last of two applications of the 15% G formulation including a banded application at-planting of 1.2 oz ai/1000 ft of row and a postemergence incorporated banded application of 2.4 oz ai/1000 ft of row (3.9 lb ai/field A seasonal use rate). Tests must be conducted in the States of FL(7%), IL(6%), MN(20%) or WI(20%), and OR(10%) or WA(10%) collectively representing ca. 70% of 1985 U.S. sweet corn production for fresh market and processing (Agricultural Statistics 1986, p. 156). The registrant must propose label amendments establishing a PHI for sweet corn K+CWR that is reflected in the data requested above. The data requested for field corn grain will be translated to support the tolerance for popcorn grain.

12/ A processing study is required depicting terbufos residues of concern in products (starch, crude oil and refined oil from wet milling; grits, meal, flour, crude oil and refined oil from dry milling; and grain dust) processed from field corn grain bearing measurable, weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

13/ Data are required depicting residues of terbufos and its cholinesterase-inhibiting metabolites in or on grain from sorghum planted in 20-inch rows and harvested at normal crop maturity following a single application of the 15% G formulation at 2.4 oz ai/1000 ft of row (3.9 lb ai/field A). The insecticide must be drilled in at bedding or at-planting 1 to 4 inches below and 0 to 5 inches to the side of the seed. Tests must be conducted in KS(20%), MO(11%), NE(14%), and TX(22%), collectively representing ca. 70% of 1985 U.S. grain sorghum production (Agricultural Statistics 1986, p. 52).

14/ A processing study is required depicting terbufos residues of concern in flour, starch, and grain dust processed from sorghum grain bearing measurable weathered residues. If residues concentrate in any product, appropriate food/feed additive tolerances must be proposed.

Table A
Generic Data Requirements for Terbufos (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

15/ Data are required depicting terbufos residues of concern in or on forage and fodder of field corn grown in 30-inch rows and harvested 30 days after application of the 15% G formulation banded at-planting at 1.2 oz ai/1000 ft of row and incorporated postemergence in a band at 2.4 oz ai/1000 ft of row (seasonal use rate of 3.9 lb ai/field A). Tests must be conducted in IL(17%) or IA(19%), IN(9%) or MI(3%) or OH(6%), MN(8%) or WI(4%), and NE(11%) or KS(2%) collectively representing ca. 80% of 1985 U.S. corn production (Agricultural Statistics 1986, p. 32).

16/ Data are required depicting terbufos residues of concern in or on forage and fodder of field corn grown in 30-inch rows and harvested 45 days after the last of three applications of the 15% G formulation, including a banded application at-planting of 1.2 oz ai/1000 ft of row, a postemergence banded application at cultivation of 1.2 oz ai/1000 ft of row, and a postemergence broadcast application of 1 lb ai/A applied by aerial or ground equipment (seasonal use rate of 3.6 lb ai/field A). Tests must be conducted in IA, NE, and NM, the States having SLN registrations that allow the postemergence broadcast applications. Alternatively, the registrant may elect to cancel the SLN registrations for postemergence broadcast use on field corn.

17/ Data are required depicting residues of terbufos and its cholinesterase-inhibiting metabolites in or on forage and fodder of sorghum grown in 20-inch rows and harvested at the PHI/PGI following a single application of the 15% G formulation at 2.4 oz ai/1000 ft of row (3.9 lb ai/field A). The insecticide must be drilled in at bedding or at-planting 1 to 4 inches below and 0 to 5 inches to the side of the seed. The registrant must propose label amendments establishing a PGI/PHI that is reflected in the data requested above. Tests must be conducted in KS(20%), MO(11%), NE(14%), and TX(22%), collectively representing ca. 70% of 1985 U.S. grain sorghum production (Agricultural Statistics 1986, p. 52).

18/ Upon receipt of the required animal metabolism data, the need for and nature of tolerances for residues of terbufos and its cholinesterase-inhibiting metabolites in meat, milk, poultry, and eggs will be reevaluated.

Table A
Generic Data Requirements for Terbufos

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission1/
§158.290 Environmental Fate						
Degradation Studies - Lab:						
161-1 - Hydrolysis	PAIRA	A	Yes	00087694	No	
Photodegradation						
161-2 - In Water	PAIRA	A	Partial	000161567	Yes2/	9 Months
161-3 - On Soil	PAIRA or TGAI	A	No	--	Yes3/	9 Months
161-4 - In Air	PAIRA or TGAI	A	No	--	Yes3/	9 Months
Metabolism Studies - Lab:						
162-1 - Aerobic Soil	PAIRA	A	Yes	00156853	No	
162-2 - Anaerobic Soil	PAIRA or TGAI	A	No	--	Yes4/	27 Months
162-3 - Anaerobic Aquatic	PAIRA or TGAI	--	No	--	No5/	
162-4 - Aerobic Aquatic	PAIRA or TGAI	--	No	--	No6/	
Mobility Studies:						
163-1 - Leaching and Absorption/ Desorption	PAIRA	A	No	--	Yes7/	12 Months
163-2 - Volatility (lab)	TEP	A	No	--	Yes8/	12 Months
163-3 - Volatility (field)	TEP	A	No	--	Reserved9/	

Table A
Generic Data Requirements for Terbufos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission1/
§158.290 Environmental Fate						
Dissipation Studies - Field:						
164-1 - Soil	TEP	A	No	--	Yes10/	27 Months
164-2 - Aquatic (Sediment)	TEP	--	No	--	No6/	
164-3 - Forestry	TEP	--	No	--	No11/	
164-4 - Combination and Tank Mixes		--	No	--	No12/	
164-5 - Soil, Long-Term	TEP	--	No	--	Reserved13/	
Accumulation Studies:						
165-1 - Rotational Crops (Confined)	PAIRA	A	Yes	00087692	No	
165-2 - Rotational Crops (Field)	TEP	A	Partial	000161568 000161569	Yes14/	50 Months
165-3 - Irrigated Crops	TEP	--	No	--	No15/	
165-5 - In Fish	PAIRA/TGAI	A	No	--	Yes16/	12 Months
163-5 - In Aquatic Nontarget Organisms	TEP	--	No	--	No5/	
Monitoring Studies:						
Soil, Water, Sediment, and Fish	TEP	A	No	--	Yes17/	6 Months (acceptable protocol)

Table A
Generic Data Requirements for Terbufos (cont'd)

§158.290 Environmental Fate Footnotes

1/ Due dates refer to the number of months following issuance of this Registration Standard unless otherwise indicated.

2/ Full information is needed on light source spectral characteristics, use and effect of filters, and comparison with natural sunlight. Also, the T 1/2 of the dark control vis a vis the hydrolysis T 1/2 and the pH of the solutions is needed before the study can be accepted.

3/ This study is required to support the current method of nonsoil-incorporated, broadcast (ground or aerially) application of the granular formulation.

4/ The study must be repeated due to low residue recoveries (material balance); also, the study should use terbufos ^{14}C-labeled in two sites to detect all degradates. The study is needed so that all the degradates present are known and can be looked for in the field dissipation study.

5/ This study is not required to support the current use pattern which does not include aquatic, forestry, or aquatic impact uses.

6/ This study is not required to support the current use pattern which does not include aquatic or aquatic impact uses.

7/ This study must be repeated due to low residue recovery for the aged and unaged studies (< 60% of applied). Such poor recovery prevents us from knowing if significant amounts of residues leached. An aged column leaching study using sand or loamy sand plus one other representative soil is required. Samples must be analyzed for both terbufos and its sulfone and sulfoxide degradates.

8/ This study is required unless the vapor pressure of the TEP (granular formulation) is less than 10^{-6} mmHg.

9/ This study is reserved pending the results of the lab volatility study.

10/ This study is required because of the many deficiencies of the reviewed studies, an important one being that the first sampling was taken 40 days posttreatment, by which time > 85% of terbufos dissipated. This deficiency is important because of the lack of information we have on leaching, and its relatively long aerobic soil half-life for parent/degradates. Samples were only taken to a depth of 6 inches and residues were present at the 3 to 6 inch depth. Samples must be analyzed for both terbufos and its sulfone and sulfoxide degradates.

11/ This study is not required to support the current use pattern which does not include forestry uses.

12/ There are no current registered combination or tank mixes for terbufos.

13/ The requirement for this study is reserved pending the results of the field dissipation study (§164-1).

14/ The two studies may be acceptable provided sample storage stability data are supplied.

15/ This study is not required to support the current use pattern which does not include aquatic uses.

16/ This study must be repeated because the treated soil was aged 30 days before adding water and fish, the test material exceeded 1/10 LC_{50}, and a flow-through system was not used to maintain a level concentration of terbufos. The study is required to determine if accumulation in fish occurs since terbufos is very toxic to fish and the corn/sorghum use has the potential to reach fish in ponds.

Table A
Generic Data Requirements for Terbufos (cont'd)

§158.290 Environmental Fate Footnotes (cont'd)

17/ The objective of this monitoring requirement is to measure actual residues of terbufos and metabolites in treated fields and in ponds adjacent to fields where terbufos is used.

The majority of terbufos marketed is used for corn rootworm control and it seems likely that environmental concerns will arise in the corn growing areas of the U.S. The application sites chosen should possess a known application history and be adjacent to ponds. Geographic areas for sampling should include: corn belt States, plain States, and lake States.

Soil in treated fields should be monitored before and after application of terbufos. Pond water, sediment, and fish should be monitored before and after fields are treated with terbufos. The scheme of monitoring (where, when, how) should reflect the attempt to measure maximum residues. Fish samples should be analyzed for cholinesterase inhibition, as well as terbufos residues. Baseline cholinesterase levels in fish brains should be established both in the ponds at the treatment sites and in an area without any history of anticholinesterase pesticide use (e.g., ponds near pastureland, but not where hay is harvested). The pH-stat technique as described by Coppage (1971) should be used. Metabolites as well as parent levels should be monitored (Cook, et al., 1976). Additional information on this type of field study can be found in Tagatz, et al., (1974) and Coppage and Braidech (1976). Treatment rates should be at highest label rate for that site and crop. Normal agricultural practices should be followed, including repeated applications, if appropriate. If possible, some sites with a history of terbufos treatment should also be chosen.

The monitoring protocol (including analytical methodology) must be submitted to the Agency, prior to initiating the study.

Table A
Generic Data Requirements for Terbufos

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
§158.340 Toxicology						
Acute Testing:						
81-1 - Acute Oral - Rat	TGAI	A	Yes	00037467*,00037471* 00035121**,00029863**,	No	
81-2 - Acute Dermal - Rabbit	TGAI	A	Yes	00144805	No	
81-3 - Acute Inhalation - Rat	TGAI	A	Yes	00144806	No[2]/	
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A	Yes	00037472,00045379	No	
Subchronic Testing:						
82-1 - 90-Day Feeding						
- Rodent	TGAI	A	Yes	00109446,00037469	No	
- Nonrodent	TGAI	A	No		No[3]/	
82-2 - 21-Day Dermal	TGAI	A	Partial	00085169	Yes[4]/	12 Months
82-3 - 90-Day Dermal	TGAI	A	No		No[5]/	
82-4 - 90-Day Inhalation	TGAI	A	No		No[6]/	
82-5 - 90-Day Neurotoxicity	TGAI	A	No		No[7]/	

Table A
Generic Data Requirements for Terbufos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission1/
§158.340 Toxicology						
Chronic Testing:						
83-1 - Chronic Toxicity						
- Rodent	TGAI	A	Yes	00045378,00049236 40089602	No8/	
- Nonrodent	TGAI	A	Yes	40374701,00161572	No9/	
83-2 - Oncogenicity Study						
- Rat	TGAI	A	Yes	00045378,00049236	No	
- Mouse	TGAI	A	Yes	40089603	No	
83-3 - Teratogenicity						
- Rat	TGAI	A	Yes	00147533	No	
- Rabbit	TGAI	A	No		Yes	15 Months
83-4 - Reproduction 3-Generation	TGAI	A	Yes	00085172,00037473	No	
Mutagenicity Testing:						
84-2 - Gene Mutation	TGAI	A	Yes	00063209	No	
84-2 - Chromosomal Aberration	TGAI	A	Yes	00161570	No	
84-2 - Other Mechanisms of Mutagenicity	TGAI	A	Yes	00161571	No	

Table A

Generic Data Requirements for Terbufos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission1/
§158.340 Toxicology						
Special Testing:						
85-1 - General Metabolism	PAI or PAIRA	A	Yes	00087695	No	
85-2 - Domestic Animal Safety	Choice	A	No	--	No10/	

1/ Due dates refer to the number of months following issuance of this Registration Standard unless otherwise indicated.

2/ A 21-day repeated inhalation study fulfills the acute requirements.

3/ This study is not required because a long-term study is available.

4/ The available 21-day dermal study in rabbits is acceptable. However, an additional 21-day dermal study to be conducted with rats is required to support the registered use of terbufos as a nonsoil-incorporated application (using aerial or ground equipment) to corn. Red blood cell and serum cholinesterase levels should be measured after the first dose and at study termination (21 days after the start of the study) in order to establish a cholinesterase NOEL. In addition, brain cholinesterase levels should be measured at the time of terminal sacrifice (21 days). Selection of dose levels is at the discretion of the registrant.

5/ This study is not required to assess the dermal exposure associated with the current pesticidal use of terbufos.

6/ This study is not required. It is unlikely that the current pesticidal use of terbufos will involve repeated inhalation, i.e., as granular formulations.

7/ This test is not required because the results of the acute delayed neurotoxicity test were negative.

8/ The 1-year rat study (40089602) combined with the 2-year rat study (00045378 and 00049236) satisfy this 83-1 data requirement for the rodent.

9/ A 4-week dog study submitted to establish a NOEL for plasma cholinesterase inhibition (40374701) combined with the 1-year dog study (0016175) satisfies this 83-1 data requirement for the nonrodent.

10/ Testing is not required based on current registered uses. However, depending on the extent of future use in feed items and whether or not tolerances would be requested in meat and milk, a combined study can be performed for both residues and domestic animal safety determinations.

* Data citations 00037467 and 00037471, combined, satisfy this data requirement for the technical material registered under EPA Registration No. 241-241.

** Data citations 00035121 and 00029863 satisfy this data requirement for the technical material currently pending under EPA File Symbol 2749-UEL.

Table A
Generic Data Requirements for Terbufos

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A	Partial	00137760	Yes[2]	27 Months
132-2 - Soil Dissipation	TEP	A	No	--	No[3]	
133-3 - Dermal Exposure	TEP	A	Partial	00137760	No[4]	
133-4 - Inhalation Exposure	TEP	A	Partial	00137760	No[4]	
§158.440 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A	No	--	No[5]	
202-1 - Drift Field Evaluation	TEP	A	No	--	No[5]	

1/ Due dates refer to the number of months following issuance of this Registration Standard, unless otherwise indicated.

2/ The submitted study is acceptable for use in the estimation of field worker exposure to terbufos residues from application of the pesticide when applied in parts of the U.S. other than in California and the arid southwest. A dislodgeable residue dissipation study to be conducted in New Mexico is required to support continued use as an aerial or broadcast treatment in the southwestern States, i.e., where rainfall is less than 25 inches/year.

3/ Soil dissipation data are not required for the current registered use of terbufos which does not include uses on crops such as potatoes or peanuts where hand harvesting will be performed.

4/ Human-exposure monitoring data may be submitted at the registrant's option. If dermal exposure data are submitted, inhalation exposure data must also be submitted.

5/ These studies are not required to support the current application of turbufos as a granular formulation.

Table A
Generic Data Requirements for Terbufos

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1/]
§158.490 Wildlife and Aquatic Organisms						
Avian and Mammalian Testing:						
71-1 - Acute Avian Oral Toxicity	TGAI	A	Yes	00106551	No	
71-2 - Avian Subacute Dietary						
- Upland Game Bird	TGAI	A	Yes	00087717,00160387	No	
- Waterfowl	TGAI	A	Yes	00035120	No	
71-3 - Wild Mammal Toxicity	TGAI	N/A	--	--	--	
71-4 - Avian Reproduction Upland Game Bird and Waterfowl	TGAI	A	Yes	00161573,00161574	No	
71-5 - Simulated Field Testing and Actual Field Testing						
- Mammals and Birds	TEP	A	Partial	00085178,00087726, 00085180,00145854, 00085179,00085183, 00131477	Yes[2/]	December 31, 1989 (1st Annual Report)[3/]
72-1 - Freshwater Fish Toxicity						
- Coldwater Fish Species	TGAI	A	Yes	00087718,00037483	No	
	TEP	A	Yes	GS0109003	No	

Table A
Generic Data Requirements for Terbufos (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission1/
§158.490 Wildlife and Aquatic Organisms						
72-1 - Freshwater Fish Toxicity (cont'd)						
- Warmwater Fish Species	TGAI	A	Yes	00087718,00037483, 00085176	No	
	TEP	A	Yes	GS0109002	No	
Aquatic Organism Testing:						
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A	Yes	00101495,00085176	No	
	TEP	A	Yes	GS0109004	No	
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	A	No		Yes4/	12 Months
72-4 - Fish Early Life Stage	TGAI	A	No		Yes	15 Months
- Aquatic Invertebrate Life Cycle	TGAI	A	Yes	00162525	No	
72-5 - Fish - Life Cycle	TGAI	A	No	--	Reserved5/	
72-6 - Aquatic Organisms Accumulation	TGAI, PAI, or Degradation Product	A	No	--	Yes	12 Months
72-7 - Simulated Field Testing and Actual Field Testing						
- Aquatic Organisms	TEP	A	No	--	Yes6/	6 Months (Protocol)

Table A
Generic Data Requirements for Terbufos (cont'd)

§158.490 Wildlife and Aquatic Organisms Footnotes

1/ Due dates refer to the number of months following issuance of this Registration Standard, unless otherwise indicated.

2/ These data are sufficient to satisfy the Level I field study requirement. A Level II field study is required to qualify the potential effects on populations of birds, mammals, and reptiles, based on the adverse effects detected in the Level I study. The Level II study must be conducted on corn to support the current registered uses on corn. Field studies for other use patterns are reserved, pending an evaluation of the results of the corn study and an analysis of applicability to support other crop uses. In the event the corn use is dropped, the study must be conducted on sorghum.

3/ The submittal due dates were set in the Agency letter of June 3, 1987 to American Cyanamid Co. and were subsequently extended in the Agency's letter of May 9, 1988 to the company.

1st Annual Report	December 31, 1989
2nd Annual Report*	December 31, 1990
3rd Annual Report*	December 31, 1991
Final Report**	December 31, 1992

*A determination may be made at this time to conclude the study, in which case a final report will be due 3 months after notification.

**This due date applies if the study has not been determined to be concluded by earlier reviews.

4/ Though terbufos appears to be at least very highly toxic to both sheepshead minnow and mysid shrimp in the available studies, they are not acceptable because of deviation from recommended protocols and must be repeated.

5/ The need for this study is reserved pending receipt of lower tier tests and environmental fate studies.

6/ Aquatic field studies are required to support the corn use. Field studies for other use patterns are reserved, pending an evaluation of the results for corn and an analysis of applicability to support other crop uses. For either mesocosm or full field studies, the study design must include appropriate techniques to determine acute mortality and effects on productivity and diversity of fish and aquatic invertebrates. A protocol for a mesocosm or full field study must be submitted to the Agency for review. A Guidance Document is available from the Agency, which outlines an acceptable approach to mesocosm studies. This document also provides relevant, although general, guidance for full field studies, which, if selected in place of mesocosm studies, must include multiple treated ponds and control ponds. The Agency encourages registrants to consult with Ecological Effects Branch staff for guidance as needed.

Table A
Generic Data Requirements for Terbufos

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission1/
§158.590 Nontarget Insect						
Nontarget Insect Testing - Pollinators:						
141-1 - Honey Bee Acute Contact LD_{50}	TGAI	A	Yes	00066220	No	
141-2 - Honey Bee - Toxicity of Residues of Foliage	TEP	A	No		No2/	
141-4 - Honey Bee Subacute Feeding Study	Reserved3/					
141-5 - Field Testing for Pollinators	TEP	A	No		No2/	
Nontarget Insect Testing - Aquatic Insects:						
142-1 - Acute Toxicity to Aquatic Insects	Reserved4/					
142-2 - Aquatic Insect Life Cycle Study	Reserved4/					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved4/					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	Reserved4/					

Table A

Generic Data Requirements for Terbufos (cont'd)

§158.590 Product Chemistry Footnotes

1/ Due dates refer to the number of months following issuance of this Registration Standard, unless otherwise indicated.

2/ Since the current registered uses of terbufos will not result in bee exposure, honey bee testing beyond the first level (acute contact LD_{50}) is not required.

3/ Reserved pending development of test methodology. Also refer to footnote 2/.

4/ Reserved pending decision as to whether the data requirement should be established.

Table B

Product-Specific Data Requirements for Manufacturing-Use Products Containing Terbufos

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation2/	Must Additional Data Be Submitted?	Timeframe for Submission3/
§158.190 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	MP	All	No		Yes4/	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	All	Partial	00147534	Yes5/	6 Months
61-3 - Discussion of Formation of Impurities	MP	All	No		Yes6/	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	All	No		Yes7/	12 Months
62-2 - Certification of Limits	MP	All	No		Yes8/	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	All	No		Yes9/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	All	No	--	Yes10/	6 Months
63-3 - Physical State	MP	All	No	--	Yes10/	6 Months
63-4 - Odor	MP	All	No	--	Yes10/	6 Months

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Terbufos (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?1/	Bibliographic Citation2/	Must Additional Data Be Submitted?	Timeframe for Submission3/
§158.190 Product Chemistry						
Physical and Chemical Characteristics (cont'd)						
63-7 - Density, Bulk Density, or Specific Gravity	MP	All	No		Yes10/	6 Months
63-8 - Solubility	MP	All	1/	1/	Yes	6 Months
63-9 - Vapor Pressure	MP	All	1/	1/	Yes	6 Months
63-12 - pH	MP	All	No		Yes10/,11/	6 Month
63-14 - Oxidizing or Reducing Action	MP	All	No		Yes10/,12/	6 Month
63-15 - Flammability	MP	All	No		Yes10/,13/	6 Months
63-16 - Explodability	MP	All	No		Yes10/,14/	6 Months
63-17 - Storage Stability	MP	All	No		Yes10/	15 Months
63-18 - Viscosity	MP	All	No		Yes10/,15/	6 Months
63-19 - Miscibility	MP	All	No		Yes10/	6 Months
63-20 - Corrosion Characteristics	MP	All	No		Yes10/	15 Months
Other Requirements						
64-1 - Submittal of Samples	N/A					

Table B
Product-Specific Data Requirements for Manufacturing-Use (cont'd)

§158.190 Product Chemistry Footnotes

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ These data citations pertain to the terbufos manufacturing-use product currently registered under EPA Registration No. 241-241 and may not be applicable to manufacturing-use products which differ from that described herein.

3/ Due dates refer to the number of months following the issuance of this Registration Standard, unless otherwise indicated.

4/ The chemical name and nominal concentration of each impurity for which a certified limit is required must be submitted. In addition, the chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredient, the following must also be provided: the product name, trade name, and common name; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

5/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

6/ A detailed discussion of all toxicologically significant impurities and all impurities that are or may be present at ≥ 0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

7/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

8/ Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at ≥ 0.1% (w/w) and each "toxicologically significant" impurity present at < 0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certifications must be submitted on EPA Form 8570, Rev. 2-85.

9/ Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

Table B
Product-Specific Data Requirements for Manufacturing-Use (cont'd)

§158.190 Product Chemistry Footnotes (cont'd)

10/ Physicochemical characteristics (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibilty, and corrosion characteristics) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.
11/ Required if the test substance is dispersible with water.
12/ Required if the product contains an oxidizing or reducing agent.
13/ Required if the product contains combustible liquids.
14/ Required if the product is potentially explosive.
15/ Required if the product is a liquid.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing Terbufos

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation2/	Must Additional Data Be Submitted?	Timeframe for Submission1/
§158.340 Toxicology					
Acute Testing:					
81-1 - Acute Oral - Rat	MP	Yes	00037467,00037471	No	
81-2 - Acute Dermal	MP	Yes	00144805	No	
81-3 - Acute Inhalation - Rat	MP	Yes	0001448063/	No	
81-4 - Primary Eye Irritation - Rabbit	MP	No		No4/	
81-5 - Primary Dermal Irritation	MP	No		No4/	
81-6 - Dermal Sensitization	MP	No	--	No4/	

1/ Due dates refer to the number of months following issuance of this Registration Standard, unless otherwise indicated.

2/ These data citations pertain to the manufacturing-use (MP) currently registered under EPA Registration No. 241-241, and may not be applicable to MPs which differ from that described herein.

3/ A 21-day repeated inhalation study fulfills the acute requirements.

4/ These data are not required because mortality would occur before sensitization or irritation.

II. LABELING APPENDICES

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container.
[40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40CFR 162.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the

Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

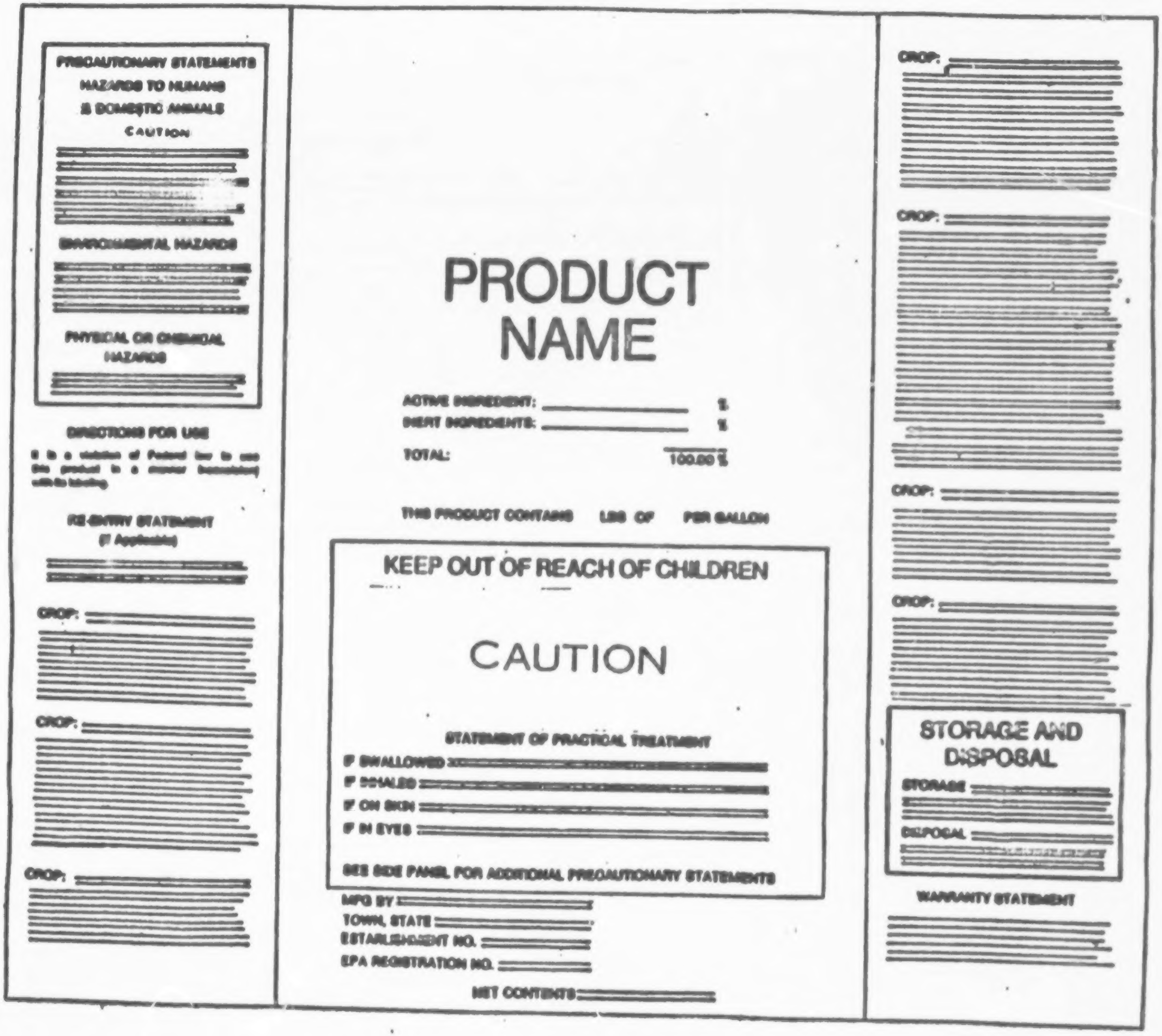
Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

08



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
& DOMESTIC ANIMALS
CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT
NAME

ACTIVE INGREDIENT: ______ %
INERT INGREDIENTS: ______ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

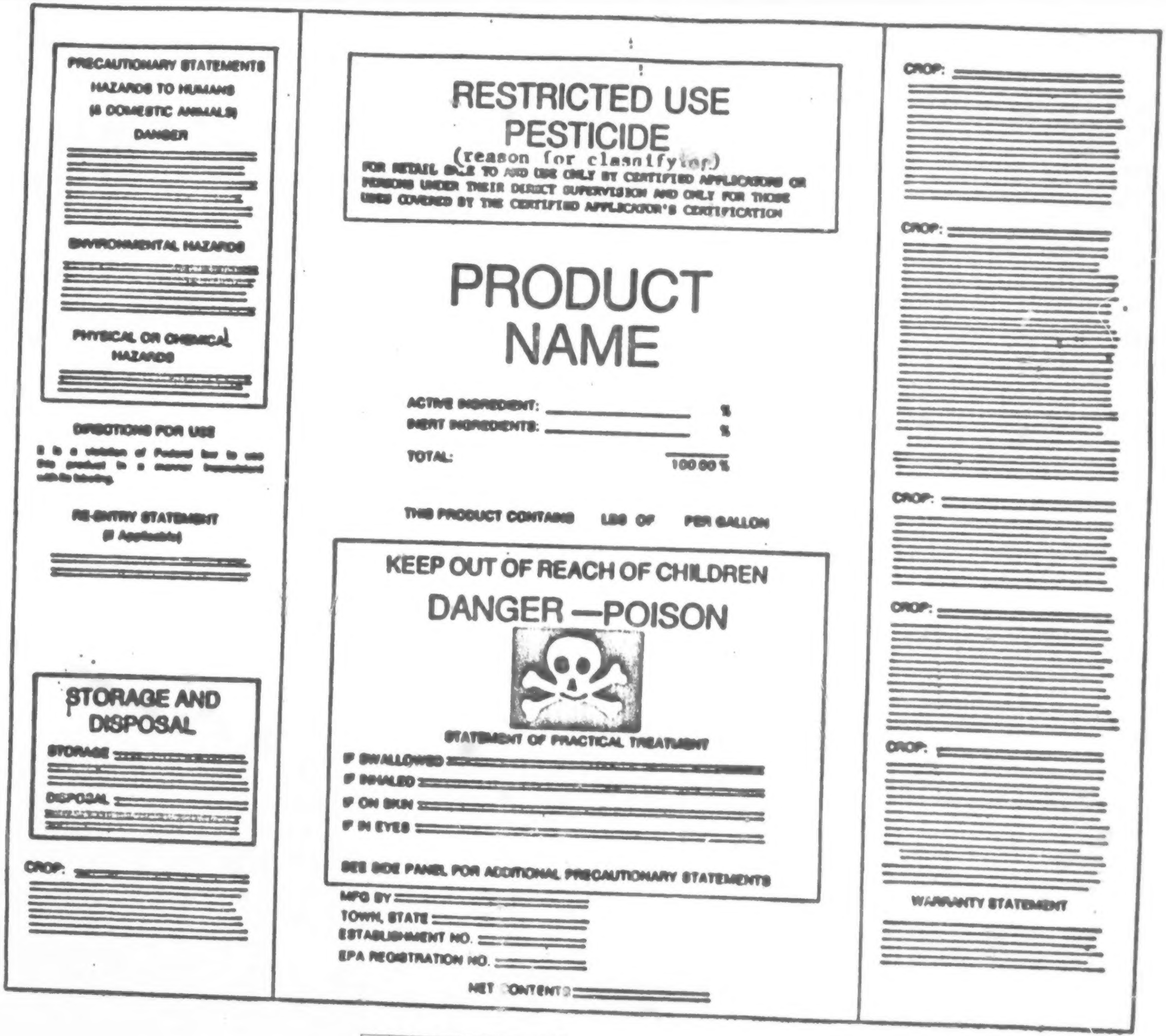
CROP:

CROP:

STORAGE AND DISPOSAL

STORAGE
DISPOSAL

WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

(& DOMESTIC ANIMALS)

DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE PESTICIDE
(reason for classifying)

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT NAME

ACTIVE INGREDIENT: %
INERT INGREDIENTS: %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.
NET CONTENTS

CROP:

CROP:

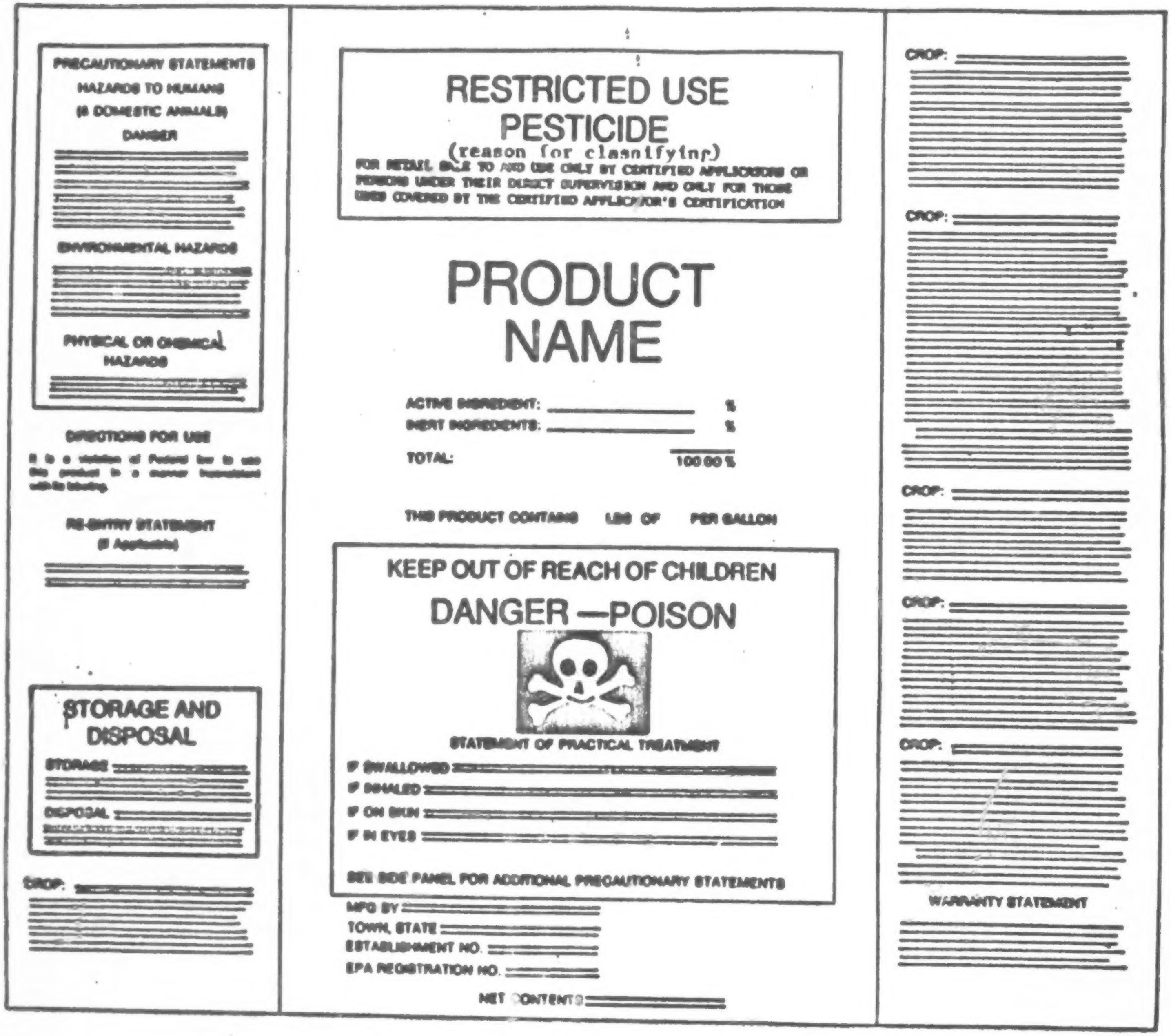
CROP:

CROP:

CROP:

WARRANTY STATEMENT

Reproduced from best available copy.



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

(& DOMESTIC ANIMALS)

DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT

(If Applicable)

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

CROP:

RESTRICTED USE PESTICIDE

(reason for classifying)

FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT NAME

ACTIVE INGREDIENT: ______ %

INERT INGREDIENTS: ______ %

TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED

IF INHALED

IF ON SKIN

IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY

TOWN, STATE

ESTABLISHMENT NO.

EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

Reproduced from best available copy.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words'"RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of

Reproduced from
best available copy.

registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD$_{50}$	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC$_{50}$	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD$_{50}$	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversable within 7 days	Corneal opacity reversable within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversable within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use—*(1) *General requirements—*(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) ***Exceptions to requirement for direction for use***—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use* The directions for use shall includ the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Direction for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal la to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as fo example the crops, animals, areas, o objects to be treated.

(iv) The target pest(s) associate with each site.

(v) The dosage rate associated wit each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effectiv results without causing unreasonabl adverse effects on the environment.

(viii) Specific limitations on reentr to areas where the pesticide has bee applied, meeting the requirement concerning reentry provided by 4 CFR Part 170.

(ix) Specific directions concernin the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. Thes instructions shall be grouped an appear under the heading "Storag and Disposal." This heading must b set in type of the same minimum siz as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions o use required to prevent unreasonabl adverse effects, such as:

(A) Required intervals between application and harvest of food or fee crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

   b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Revised Terbufos Standard

00029863 Consultox Laboratories (1975) Acute Oral and Percutaneous Toxicity Evaluations. (Unpublished study received Feb 3, 1976 under 2749-425; submitted by Aceto Chemical Co., Inc., Flushing, N.Y.; CDL:241780-A)

00032636 Fischer, J.E. (1979) Toxicity Data Report: Report No. A79-109. (Unpublished study received Jun 11, 1980 under 241-260; submitted by American Cyanamid Co., Princeton, N.J.; CDL:099451-B)

00032646 Palochak, M.E.; Shapiro, R.L. (1971) Microbiology Laboratory Report: Report No. 710903M1. (Unpublished study received Jan 19, 1971 under 52-127; prepared in cooperation with Hudson Laboratories, Inc., submitted by West Chemical Products, Inc., Lynbrook, N.Y.; CDL:000053-A)

00035120 Krize, J.W.; Terrel Y. (1978) Report: Avian Dietary LC_{50} (5-Day Dietary Exposure) of Enlist Technical (Terbufos Technical) EPA File Symbol 2749-UEL to Mallard Duck; Laboratory No. 8E-3451. (Unpublished study received Mar 27, 1979 under 2749-425; prepared by Cannon Laboratories, Inc., submitted by Aceto Chemical Co., Inc., Flushing, N.Y.; CDL:241730-A)

00035121 Parke, G.S.E.; Terrell, Y. (1976) Acute Oral Toxicity in Rats: Compound: Enlist Technical Insecticide (Terbufos) EPA File Symbol 2749-UEL: Laboratory No. 6E-3164. (Unpublished study received Nov 29, 1976 under 2749-425; prepared by Cannon Laboratories, Inc., submitted by Aceto Chemical Co., Inc., Flushing, N.Y.; CDL:241733-A)

00036123 Caballa, S.H.; Ku, C.; Miller, P.; et al. (1975) Summary--Metabolism of Counter (CL 92,100) in Sugar Beets. (Unpublished study including project no. 2-404 and report nos. C-698 and M-606, received Jun 10, 1975 under 5F1640; submitted by America Cyanamid Co., Princeton, N.J.; CDL:094445-G)

00036124 Higham, J.W.; Alvarez, C.G.; Burhardt, C.C.; et al. (1975) General Summary: Counter(R) 15G Soil Insecticide Residues in Sugar Beet Tops and Roots. (Unpublished study received Jun 10, 1975 under 5F1640; submitted by American Cyanamid Co., Princeton, N.J.; CDL:094445-H)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Revised Terbufos Standard

00036127 Higham, J.W.; Peterson, R.P. (1974) CL 92,100 and 92,100 Related Compounds: Gas Chromatographic Procedure for the Determination of CL 92,100 in Sugar Beet Tops (Greens) and Roots. Includes method M-395 dated Mar 1, 1973. (Unpublished study including report no. C-532, received Jun 10, 1975 under 5F1640; submitted by American Cyanamid Co., Princeton, N.J.; CDL:094445-K)

00036129 Peterson, R.P.; McGinnis, R.A. (1975) Counter (CL 92,100): Total Counter-Related Residues in Sugar Beet Dried Pulp and Juice (Thick and Thin): Report No. C-679. Includes method no. M-501 dated May 1, 1975. (Unpublished study received Jun 10, 1975 under 5F1640; prepared in cooperation with Spreckels Sugar co., submitted by American Cyanamid Co., Princeton, N.J.; CDL:094445-M.

00036241 Manuel, A.J. (1972) Total CL 92,100 and Its Metabolites in Milk: Report No. C-336. Includes method M-353 dated Jul 31, 1972. (Unpublished study received Apr 9, 1973 under 3G1340; submitted by American Cyanamid Co., Princeton, N.J; CDL:093581-J)

00036242 Manuel, A.J.; Peterson, R.P.; Potts, C.R.; et al. (1972) CL 92,100 and Its Metabolites in Cattle Fat, Muscle, Liver and Kidney: Report No. C-337. Includes method M-372 dated Nov 9, 1972. (Unpublished study received Apr 9, 1973 under 3G1340; submitted by American Cyanamid Co., Princeton, N.J.; CDL:093581-K)

00036246 American Cyanamid Company (1972) CL-92100: Determination of Total CL-92100-Related Residues in Corn Forage and Grain. Method M336 dated Jun 21, 1972. (Unpublished study received Apr 9, 1973 under 3G1340; CDL:093582-C)

00037467 American Cyanamid Company (1972) Toxicity Data: O,O-Diethyl-S (tert-butylthiomethyl) phosphorodithioate Technical, 85.8% AC 2162-42: Report A-72-95. (Unpublished study received Apr 9, 1973 under 3G1340; CDL:093584-B)

00037469 Sabol, R.J.; Smith, J.M.; Wilson, N.H.; et al. (1972) A 3 and 24 Month Oral Toxicity and Carcinogenicity Study of AC 92, 100 in Rats: Three Month Report: Project No. 71R-725. (Unpublished study received Apr 9, 1973 under 3G1340; prepared by Bio/dynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:093584-D)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Revised Terbufos Standard

00037471 Kretchmar, B. (1972) Report to American Cyanamid: Acute Oral Toxicity Studies with Two Samples in Female Albino Rats: IBT No. A1373. (Unpublished study received Apr 9, 11973 under 3G1340; prepared by Industrial Bio-Test Laboratories, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:093584-G)

00037472 Smith, J.H.; Rosselet, C.; Cannelongo, B.; et al. (1972) A Neurotoxicity Study of AC 92,100, an Organic Phosphate Cholinesterase Inhibitor, in Hens: Project No. 72S-788. (Unpublished study received Apr 9, 1973 under 3G1340; prepared by Bio/dynamics, Inc. submitted by American Cyanamid Co., Princeton, N.J.; CDL: 093584-H)

00037473 Smith, J.M.; Kasner, J. (1972) Status Report for American Cyanamid Company, November 28, 1972: A Three Generation Reproduction Study of AC 92,100 in Rats: Project No. 71R-727. (Unpublished study received Apr 9, 1973 under 3G1340; prepared by Bio/dynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:093584-I)

00037483 Sleight, B.H., III (1972) The Acute Toxicity of Cycocel™(R) and Experimental Insecticide AC 92,100 to Bluegill (Lepomis maclished study received Apr 9, 1973 under 3G1340; prepared by Bionomics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:093584-U)

00039018 American Cyanamid Company (1974) General Summary: Counter Related Residues in Immature Corn Commodities from In-Furrow Application of Counter™(R) 15G Soil Insecticide at Planting. Summary of studies 094895-D through 094895-G. (Unpublished study received 1976 under 6F1657; CDL:094895-C)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Revised Terbufos Standard

00042017 American Cyanamid Company (1973) Summary--Counter-Related Residues in Corn. (Unpublished study received May 1, 1974 under 4F1496; CDL:091452-A)

00042019 Higham, J.W.; Manuel, A.J.; Peterson, R.P.; et al. (1974) Efficacy of Counter and Other Herbicides on Corn: Report No. C-415. Includes method M-336 dated Jun 21, 1972. (Unpublished study including report nos. C-416 and C-425, received May 1, 1974 under 4F1496; prepared in cooperation with Quality Control Laboratories and others, submitted by American Cyanamid Co., Princeton, N.J.; CDL:091452-C)

00042020 Higham, J.W.; Manuel, A.J.; Congleton, W.F.; et al. (1974) Counter™(R) 15G: Total Counter (CL 92,100)-Related Residues in Soybean Commodities: Immature Plant, Harvest Plant and Harvest Beans (Kansas and Iowa): Report No. C-429. Includes method M-480 dated Jan 9, 1974. (Unpublished study received May 1, dustries and Iowa State Univ., Dept. of Zoology & Entomology, submitted by American Cyanamid Co., Princeton, N.J.; CDL: 091452-D)

00042021 Manuel, A.J.; Elenewski, C.A. (1974) Counter (CL 92,100) Stability of Residues in Counter-Treated Corn Grain and Forage Samples When Stored in the Frozen State: Report No. C-430. Includes method M-336 dated Jun 21, 1972. (Unpublished study received May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL:091452-F)

00042022 Manuel, A.J. (1973) Counter (CL 92,100): Confirmatory Gas-Liquid Chromatography Test for Counter Residues in Corn Grain and Forage, and in Animal Tissues: Report No. C-379. Includes method M-460 dated Sep 27, 1973. (Unpublished study received May 1, 1974 under 4F1490; submitted by American Cyanamid Co., Princeton, N.J.; CDL:091452-G)

OFFICE OF PESTISCIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Revised Terbufos Standard

00045378 Smith, J.M.; Kasner, J.A. (1973) Status Report for American Cyanamid--March 9, 1973; A Three and Twenty-Four Month Oral Toxicity and Carcinogenicity Study of AC 92,100 in Rats--11 Month Status of Eye Observations: Project No. 71R-725. (Unpublished study received Apr 9, 1973 under 3G1340; prepared by Bio/dynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:093580-A)

00045379 Smith, J.M.; Willigan, D.A. (1973) A Neurotoxicity Study of AC 92,100, an Organic Phosphate Cholinesterase Inhibitor in Hens: Project No. 72S-788. (Addendum I; unpublished study received Apr 9, 1973 under 3G1340; prepared by Bio/dynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL:093580-B)

00049235 Snyder, E.H. (1975) Counter(R) (CL 92,100): The Gas Chromatographic Determination of CL 92, 100 (0,0-Diethyl) SButylthiomethyl-phosphorodithioate)-Related Residue in Fortified Barley, Green Beans, Red Beets and Wheat: Report No. C-730. (Unpublished study received Oct 9, 1975 under 241-238; submitted by American Cyanamid Co., Princeton, N.J.; CDL:224099-C)

00049236 Rapp, W.R.; Wilson, N.H.; Mannion, M.; et al. (1974) A Three and Twenty-Four Month Oral Toxicity and Carcinogenicity Study of AC 92,100 in Rats: Project No. 71R-725. (Unpublished study received May 29, 1975 under 241-238; prepared by Biodynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL: 224096-A)

00062871 Peterson, R.P. (1976) Counter(R) Insecticide 15-G and Liquid (CL 92,100): Metabolism of 14C-Labeled CL 92,100 ... in Cabbage Plants: PD-M 13-1:1-19. (Unpublished study received Nov 3, 1980 under 241-238; submitted by American Cyanamid Co., Princeton, N.J.; CDL:099682-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Revised Terbufos Standard

00062872 American Cyanamid Company (1976) Residue Studies in Cabbage, Broccoli and Cauliflower. (Compilation; unpublished study received Nov 3, 1980 under 241-238; CDL:099682-B)

00063209 Allen, J.S.; Johnson, E.; Wainwright, C. (1977) Mutagenicity Testing of Technical Counter"(R) Soil Insecticide (Terbufos) in the Ames Test: AIR 5:419-431. Final rept. (Unpublished study received Apr 17, 1978 under 241-241; submitted by American Cyanamid Co., Princeton, N.J.; CDL:234103-B)

00066220 Atkins, E.L., Jr.; Anderson, L.D.; Kellum, D.; et al. (1976) Protecting Honey Bees from Pesticides. ?: Univ. of California, Div. of Agricultural Sciences. (Leaflet 2883; also In unpublished submission received Mar 20, 1980 under 432-502; submitted by Penick Corp., Lyndhurst, N.J.; CDL:243536-B)

00069512 North, H.H.; Barringer, D.F.; Gatterdam, P.E.; et al. (1972) CL 92,100 Insecticide: Fate of C"14-Labeled CL 92,100 in Sweet Corn Plants: PDM 9:249-301. (Unpublished study received on unknown date under 241-EX-59; submitted by American Cyanamid Co., Princeton, N.J.; CDL:223458-X)

00079429 Chiu, T.Y.; Lucas, L.M. (1981) Counter"(TM) Terbufos (CL 92,100): 18-16:1-43. (Unpublished study received Jul 13, 1981 under 241-238; submitted by American Cyanamid Co., Princeton, N.J.; CDL:070186-A)

00079430 American Cyanamid Company (1980) Residue Studies with Counter(R) 15-G Soil Insecticide-Nematicide in Sorghum. (Compilation; unpublished study received Jul 13, 1981 under 241-238; CDL:070186-B)

00079431 Peterson, R.P.; Good, T. (1979) Counter"(R) Terbufos (CL 92,100): Validation of GC Method M-0995 for the Determination of Total CL 92,100-Related Residues in Sorghum Tissues (Silage, Fodder and Grain): Report No. C-1592. Includes method M-995 dated Jul 11, 1979. (Unpublished study received Jul 13, 1981 under 241238; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 070186-C)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Revised Terbufos Standard

00085169 Kruger, R.; Feinman, H.; (1973) 30-day Subacute Dermal Toxicity in Rabbits of AC-92100: Laboratory No. 1611. (Unpublished study received May 1, 1974 under 4F1496; prepared by Food and Drug Research Laboratories, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL: 090808-J)

00085172 Smith, J.M.; Kasner, J.A.; Wilson, N.H.; et al. (1972) A Three Generation Reproduction Study of Pesticide AC 92,100 in Rats: Project No. 71R-727. (Unpublished study received May 1, 1974 under 4F1496; prepared by Bio/dynamics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL: 090808-M)

00085176 Bentley, R.E. (1973) Acute Toxicity of Counter™(TM) to Bluegill (Lepomis macrochirus), Channel Catfish (Ictalurus punctatus) and Crayfish (Procambarus clarkii). (Unpublished study received May 1, 1974 under 4F1496; prepared by Bionomics, Inc., submitted by American Cyanamid Co., Princeton, N.J.; CDL: 090808-Q)

00085178 Labisky, R.F.; Anderson, W.L. (1973) Effects of Field Applications of Counter™(R) Soil Insecticide on Wildlife. (Unpublished study received May 1, 1974 under 4F1496; prepared by Illinois Natural History Survey, submitted by American Cyanamid Co., Princeton, N.J.; CDL: 090808-T)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Revised Terbufos Standard

00085179 Labisky, R.F. (1974) Responses of Confined Hen Pheasants to Simulated Field Applications of Counter(R) Soil Insecticide. (Unpublished study received May 1, 1974 under 4F1496; prepared by Illinois Natural History Survey, submitted by American Cyanamid Co., Princeton, N.J.; CDL: 090808-U)

00085180 Manuel, A.J. (1973) Counter(TM) 15G Soil Insecticide; CL 92,100 and Its Metabolites in Wildlife Tissues and Eggs: Report No. C377. (Unpublished study received May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 090808-V)

00085183 Manuel, A.J. (1973) Counter(TM) (CL 92,100) Related Residues in Pheasant Muscle, Liver, Skin, Kidney and Fat: Report No. C378. (Unpublished study received May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 090808-Y)

00087686 Higham, J.W.; North, H.H. (1974) Counter(R) 15G: CL 99875 (Metabolite 13) Residue in Corn Silage and Fodder: Report No. C-437. (Unpublished study received May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 091409-C)

00087687 Higham, J.W. (1974) CL 99, 875: The Determination of CL 99,875 in Corn Silage and Fodder. Method M-489 dated Feb 19, 1974. (Unpublished study received May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 091409-D)

00087688 North, H.H.; Jenney, K. (1974) Counter(R) Soil Insecticide: Residue Levels and Metabolism in Sweet Corn Foliage and Grain: Report No. 442. (Unpublished study received May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 091409-E)

00087689 Barringer, D.F.; Gatterdam, P.; Steller, W.A. (1973) CL 92,100 Counter(R) Insecticide: The Identification of the Major Metabolites Found in Mature Sweet Corn Plants and in Soil: PD-M 10: 423-454. Progress rept., Jun 27, 1972 through Mar 30, 1973. (Unpublished study received May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL: 091409-F)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Revised Terbufos Standard

00087691 Caballa, S.; Ku, C.; Miller, P. (1973) Counter"(R) Insecticide (15-G): Metabolism of "14C-Labeled CL 92,100 in Sugar Beets: Report No. C-405. (Unpublished study received May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL:091409-H)

00087692 Gatterdam, P.; Jenney, K. (1974) Counter"(R) Soil Insecticide: Residue Levels in Soybeans Grown as a Follow Crop on Soil Previously Treated with "14C-CL 92,100: Report No. C-422. (Unpublished study received May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL;091409-I)

00087694 Metabolic Studies of "14C-labeled CL 92,100 in Hydrolytic and Photolytic Environments: PD-M 10:959-1007. Progress rept., Apr 5, 1973 through Oct 15, 1973. (Unpublished study received May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL:091409-K)

00087695 North, H.H. (1973) Counter"(R) Insecticide: Rat Metabolism of CL 92, 100 PD-M 10:1008-1080. Progress rept., Mar 1, 1973 through Sep 28, 1973. (Unpublished study recieved May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL:091409-L)

00087702 Manuel, A.J. (1973) CL 92,100 and Its Metabolites in Chicken Fat, Muscle, Liver, Kidney, Skin, and Eggs: Report No. C-372. (Unpublished study received May 1, 1974 under 4F1496; submitted by American Cyanamid Co., Princeton, N.J.; CDL:091837-B)

00087704 American Cyanamid Company (1973) CL 92,100: Determination of Total CL 92,100 and Oxidative Metabolites in Chicken Fat, Muscle, Skin, Liver, and Kidney by Gas Liquid Chromatography. Method M-401 dated Mar 15, 1973. (Unpublished study received May 1, 1974 under 4F1496; CDL:091837-D)

00087717 Roberts, S.; Wineholt, R.L. (1976) 81-day Dietary LC50 Study of Terbufos in Bobwhite Quail and Mallard Duck: Laboratory No. 6E3165. (Unpublished study received Nov 24, 1976 under 2749-427; prepared by Cannon Laboratories, Inc., submitted by Aceto Chemical Co., Inc., Flushing, N.Y.; CDL:226950-A)

00087718 Roberts, S.; Wineholt, R.L. (1976) Static 96-hour Toxicity Study of Terbufos in Bluegill Sunfish and Brown Trout: Laboratory No. 6E-3166. (Unpublished study received Nov 24, 1976 under 2749-427; prepared by Cannon Laboratories, Inc., submitted by Aceto Chemical Co., Inc., Flushing, N.Y.; CDL:226951-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Revised Terbufos Standard

00087722 American Cyanamid Company (1972) Residue of AC 92,100 in Corn. Includes method M-336 dated Jun 21, 1972. (Compilation; unpublished study, including report nos. C-335, 72-43, 82-47, received on unknown date under 241-EX-3; CDL:123080-E)

00087724 American Cyanamid Company (1975) [Residues of Counter(R) 15G in Corn and Popcorn]. Includes method M-336 dated Jun 21, 1972. (Compilation; unpublished study, including report Nos. C-644, C-635, C-639 ..., received Apr 1, 1975 under 241-238; CDL:110506-B)

00087726 Wang, G.T. (1973) Letter sent to Harold H. Nau dated Jun 21, 1973: Post-mortem examination--wildlife. (Unpublished study received on unknown date under unknown admin. no.; submitted by American Cyanamid Co., Princeton, N.J.; CDL:223457-A)

00088210 Chiu, T.; Lucas, L.; Goldenbaum, L. (1981) Counter™(TM) Terbufos (CL 92,100): Metabolism of Carbon-14 Labeled CL 92,100 in Soybean: Report No. PD-M 18-19:1-65. (Unpublished study received Dec 1, 1981 under 241-238; submitted by American Cyanamid Co., Princeton, N.J.; CDL:070496-A)

00088211 American Cyanamic Company (1981) General Summary: Counter 15-G. (Compilation; unpublished study received Dec 1, 1981 under 241238; CDL:070496-B)

00101495 Boudreau, P.; Forbis, A.D.; Franklin, L.; et al. (1982) Acute Toxicity of Counter® Terbufos to Daphnia magna: Static Acute Bioassay Report 28686. (Unpublished study received Apr 20, 1982 under 241-238; submitted by American Cyanamid Co., Princeton, N.J., CDL:247247-C)

00106551 Fink, R.; Beavers, J.B.; Joiner, G.; et al. (1982) Final Report: Acute Oral LD$_{50}$ -- Bobwhite Quail: Counter® Terbufos Technical: Project No. 130-133. (Unpublished study received Apr 20, 1982 under 241-238; submitted by American Cyanamid Co., Princeton, N.J.; CDL:247247-B)

00109446 Daley, I.; Rinehart, W.; Martin, A. (1979) A Three Month Feeding Study of Counter® Terbufos Insecticide in Rats: Project No. 78-2343 (Unpublished study received ? , 1982 submitted by American Cyanamid Co., Princeton, N.J.; CDL: 247985-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Revised Terbufos Standard

0129173 American Cyanamid Company (1980) Metabolism and Residues: Counter Soil Insecticide-nematicide: Rape and Mustard. (Compilation; unpublished study received Jul 14, 1983 under 241-272; CDL:071747-C)

0131237 Mangels, G.; Goldenbaum, L. (1983) Counter Terbufos (CL 92,100): Metabolism of Carbon-14 Labeled CL 92,100 in Wheat Grain: Project No. 0427. (Unpublished study received Oct 3, 1983 under 241-238; submitted by American Cyanamid Co., Princeton, NJ; CDL:251414-C)

0131477 Labisky, R. (1975) Responses of pheasants to simulated field applications of counter, an organophosphate insecticide. Journal of Wildlife Management 39(1): 174-178. (Also in unpublished submission received Oct 6, 1983 under 241-238; submitted by American Cyanamid Co., Princeton, NJ; CDL:251469-B)

0133299 American Cyanamid Co. (1983) Metabolism and Residues: Counter Insecticide. (Compilation; unpublished study received Nov 22, 1983 under 241-238; CDL:072150-A)

0137582 American Cyanamid Co. (1984) Metabolism and Residues: Counter Soil Insecticide-nematicide in Corn Plants, Fodder and Grain. (Compilation; unpublished study received Feb 9, 1984 under 241-238; CDL:252421-A)

0137760 Peterson, R.; Picard, G.; Higham, J.; et al. (1984) Farm Worker Exposure Study with Aerial Application of Counter 15-G: Report No. C-2370. (Unpublished study received Mar 21, 1984 under 241-238; submitted by American Cyanamid Co., Princeton, NJ; CDL:252762-A)

0142295 American Cyanamid Co. (1984) [Product Chemistry for Counter]. Unpublished study. 84 p.

0144805 Fischer, J. (1985) Rabbit Dermal LD_{50} (Intact Skin): Report No. A85-54. Unpublished study prepared by American Cyanamid Co. 3 p.

0144806 Rusch, G. (1980) A Two Week Inhalation Toxicity Study of Technical Counter Terbufos in the Rat: Project No. 78-7168. Unpublished study prepared by Bio/Dynamics, Inc. 346 p.

0147533 Rodwell, D. (1985) A Teratology Study with AC 92, 100 in Rats: Project No. WIL-35014: Final Report. Unpublished study prepared by WIL Research Laboratories, Inc. 212 p.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Revised Terbufos Standard

0147534 American Cyanamid Co. (1983) Sample Identification, Purity and Minor Component Profile [Counter Terbufos]. Unpublished study. 28 p.

00156853 Peterson, R. (1983) Counter Terbufos (CL 92,100): Aerobic and Anaerobic Metabolism of CL 92,100 in a Silt Loam Soil: Project No. 0402: Report No. PD-M Volume 20-4. Unpublished study prepared by American Cyanamid Co. 52 p.

0158614 Elenewski, C. (1983) Counter Terbufos (CL 92,100): Validation of GC Method M-1340 for the Determination of Total CL 92,100-related Residues in Whole Bananas: Report No. C-2260. Unpublished study prepared by American Cyanamid Co. 13 p.

0160387 Beavers, J. (1984) A Dietary LC_{50} Study in the Bobwhite with AC 92,100: Final Report: Project No. 130-134. Unpublished study prepared by Wildlife International Ltd. 18 p.

0161567 Mangels, G. (1986) Counter Insecticide, Terbufos (CL 92,100): Water Photolysis: Report No. PD-M 23-19: Project No. 0112. Unpublished study prepared by American Cyanamid Co. 29 p.

00161568 Lee, T.; Belcher, D. (1986) Counter Terbufos (CL 92,100): Residues of CL 92,100-related Compounds in Soil and Rotational Crops (Cabbage, Red Beets, and Wheat) from a Treated Corn Field (Waunakee, WI, 1984) (C-1689, C-0532, C-0880, C-2642): Report No. C-2658: Project No. 0402. Unpublished study prepared by American Cyanamid Co. 28 p.

00161569 Lee, T.; Belcher, D. (1986) Counter Terbufos (CL 92,100): Residues of CL 92,100-related Compounds in Soil and Rotational Crops (Cabbage, Sugar Beets, and Wheat) from a Treated Corn Field (York, NE, 1984) (C-1689, C-0532, C-0880, C-2642): Report No. C-2721: Project No. 0403. Unpublished study prepared by American Cyanamid Co. 53 p.

00161570 Putman, D. (1986) The Acute in vivo Cytogenetics Assay in Rats: AC 92,100: Final Report: MA Study No. T4277.105002. Unpublished study prepared by Microbiological Associates, Inc. 44 p.

00161571 Mackenzie, K. (1986) Dominant Lethal Study with AC 92,100 in Rats: Final Report: Study No. 6123-137. Unpublished American Cyanamid Study No. 980-85-193 prepared by Hazleton Laboratories America, Inc. 147 p.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registration Under the Revised Terbufos Standard

00161572 Shellenberger, T. (1986) One-year Oral Toxicity Study in Purebred Beagle Dogs with AC 92,100: Final Report: Report No. 8414. Unpublished America Cyanamid Co. Report No. 981-84-118 prepared by Tegeris Laboratories, Inc. 836 p.

00161573 Beavers, J. (1986) Counter Technical: A One-generation Reproduction Study with the Bobwhite (Colinus Virginianus Final Report: Project No. 130-137. Unpublished study prepared by Wildlife International Ltd. 129 p.

00161574 Beavers, J. (1986) Counter Technical: A One-generation Reproduction Study with the Mallard (Anas platyrhynchos): Final Report: Project No. 130-138. Unpublished study prepared by Wildlife International Ltd. 129 p.

00162525 Forbis, A.; Land, C.; Bunch, B. (1986) Chronic Toxicity of CL 92,100 to Daphnia magna Under Flow-Through Test Conditions: ABC Final Rept. #32891. Unpublished study prepared by Analytical Bio-Chemistry Laboratories, Inc. 164 p.

40089602 Daly, I. (1987) A One-year Dietary Toxicity Study with AC 92,100 in Rats: Chronic Toxicity in Rats: Project No. 85-2964. Unpublished study prepared by Bio/dynamics, Inc. 1604 p.

40089603 Shellenberger, T. (1986) Chronic Dietary Toxicity and Oncogenicity Study with AC 92,100 in Mice: Chronic Toxicity and Oncogenicity--Mouse: Laboratory Project ID. 8422. Unpublished study prepared by Tegeris Laboratories, Inc. 1566 p.

4034701 American Cyanamid Company (1987) 28-Day Oral Toxicity Study in the Dog with AC 92,100: Unpublished study received Oct 14, 1987 under 241-241.

GS0109001 American Cyanamid Company. Residue Studies for the Use of Counter® 15G As a Cultivation Time Application for Control of Corn Rootworms. (Unpublished study received Nov 10, 1977 under 241-238; CDL:232258)

GS0109002 U.S. Environmental Protection Agency (1975). Report on the Toxicity of Counter® 15G to Bluegill Sunfish. Static Jar, Test No. 894, Nov 7, 1975; (unpublished study prepared by U.S. EPA Chemical and Biological Investigations Branch, Beltsville, MD)

GS0109003 U.S. Environmental Protection Agency (1975). Report on the Toxicity of Counter® 15G to Rainbow Trout. Static Jar, Test No. 909, Dec 12, 1975; (unpublished study prepared by U.S. EPA Chemical and Biological

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under the Revised Terbufos Standard

GS0109004 U.S. Environmental Protection Agency (1976). Report on the Toxicity of Counter® 15G to Daphnia magna. Static Jar, Test No. 922, Feb 2, 1976; (unpublished study prepared by U.S. EPA Chemical and Biological Investigations Branch, Beltsville, MD)

IV. FORMS APPENDICES

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE

SIGNATURE

DATE

EPA Form 8580-1

Reproduced from
best available copy.

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date ____________________

Guidance Document for ____________________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: ______________________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated ____________ concerning a requirement for submission of "generic" data on the active ingredient ______________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated __________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ______________________ and their registration number(s) is/are ______________ .

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________________
(Signature)

Dated: __________________ ______________________________
(Typed)

EPA Form 8570-27

2070-0060

CERTIFICATION WITH RESPECT TO CITATION OF DATA

EPA File Symbol/Reg. No. ____________ Date of application ____________

Name of Product ____

Applicant's Name and Address ____

____

____

____

1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.

2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I have obtained the written permission of the original data submitter to cite that study.

3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

I have obtained the written permission of the original data submitter to cite that study; or

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

☐ All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (Cite-all method or cite-all option under Selective Method). (Also sign the General Offer to Pay Statement below.)

☐ Those companies who have submitted the studies which I have cited (Selective method)

Date ____________ Signature ____________

Title ____________

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Date ____________ Signature ____________

Title ____________

EPA Form (April 1985)

*U.S. GOVERNMENT PRINTING OFFICE:1988-516-002:80043